

# Psychological interventions for acute pain after open heart surgery (Review)

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# Psychological interventions for acute pain after open heart surgery

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## ABSTRACT

### Background

Acute postoperative pain is one of the most disturbing complaints in open heart surgery, and is associated with a risk of negative consequences. Several trials investigated the effects of psychological interventions to reduce acute postoperative pain and improve the course of physical and psychological recovery of participants undergoing open heart surgery.

### Objectives

To compare the efficacy of psychological interventions as an adjunct to standard care versus standard care alone or standard care plus attention in adults undergoing open heart surgery on pain, pain medication, mental distress, mobility, and time to extubation.

### Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library* 2013, Issue 8), MEDLINE (1946 to September 2013), EMBASE (1980 to September 2013), Web of Science (all years to September 2013), and PsycINFO (all years to September 2013) for eligible studies. We used the 'related articles' and 'cited by' options of eligible studies to identify additional relevant studies. We also checked lists of references of relevant articles and previous reviews. We also searched the ProQuest Dissertations and Theses Full Text Database (all years to September 2013) and contacted the authors of primary studies to identify any unpublished material.

### Selection criteria

Randomised controlled trials comparing psychological interventions as an adjunct to standard care versus standard care alone or standard care plus attention in adults undergoing open heart surgery.

### Data collection and analysis

Two review authors (SK and JR) independently assessed trials for eligibility, estimated the risk of bias and extracted all data. We calculated effect sizes for each comparison (Hedges' g) and meta-analysed data using a random-effects model.

## Main results

Nineteen trials were included (2164 participants).

No study reported data on the number of participants with pain intensity reduction of at least 50% from baseline. Only one study reported data on the number of participants below 30/100 mm on the Visual Analogue Scale (VAS) in pain intensity. Psychological interventions have no beneficial effects in reducing pain intensity measured with continuous scales in the medium-term interval (g -0.02, 95% CI -0.24 to 0.20, 4 studies, 413 participants, moderate quality evidence) nor in the long-term interval (g 0.12, 95% CI -0.09 to 0.33, 3 studies, 280 participants, low quality evidence).

No study reported data on median time to remedication or on number of participants remedicated. Only one study provided data on postoperative analgesic use. Studies reporting data on mental distress in the medium-term interval revealed a small beneficial effect of psychological interventions (g 0.36, 95% CI 0.10 to 0.62, 12 studies, 1144 participants, low quality evidence). Likewise, a small beneficial effect of psychological interventions on mental distress was obtained in the long-term interval (g 0.28, 95% CI 0.05 to 0.51, 11 studies, 1320 participants, low quality evidence). There were no beneficial effects of psychological interventions on mobility in the medium-term interval (g 0.23, 95% CI -0.22 to 0.67, 3 studies, 444 participants, low quality evidence) nor in the long-term interval (g 0.29, 95% CI -0.14 to 0.71, 4 studies, 423 participants, low quality evidence). Only one study reported data on time to extubation.

## Authors' conclusions

For the majority of outcomes (two-thirds) we could not perform a meta-analysis since outcomes were not measured, or data were provided by one trial only. Psychological interventions have no beneficial effects on reducing postoperative pain intensity or enhancing mobility. There is low quality evidence that psychological interventions reduce postoperative mental distress. Due to limitations in methodological quality, a small number of studies, and large heterogeneity, we rated the quality of the body of evidence as low. Future trials should measure crucial outcomes (e.g. number of participants with pain intensity reduction of at least 50% from baseline) and should focus to enhance the quality of the body of evidence in general. Altogether, the current evidence does not clearly support the use of psychological interventions to reduce pain in participants undergoing open heart surgery.

## PLAIN LANGUAGE SUMMARY

### Psychological treatments to reduce pain in people undergoing open heart surgery

Acute postoperative pain is one of the most disturbing complaints in open heart surgery, and is related to a risk of negative consequences such as impaired wound healing, chronic pain or depression. Psychological treatment is designed to improve patients' knowledge and to alter surgery-related mental distress, negative beliefs and non-compliance. It aims to reduce pain and anxiety, and to improve the post-operative recovery after open heart surgery. Psychological treatment comprises the provision of information about medical procedures and associated emotional responses and sensations before, during and after surgery, and instructions about how to adhere to medical advice to support the recovery; teaching or instructing patients in different relaxation techniques; or helping patients to understand their thoughts and feelings that influence their behaviours.

This review investigated whether psychological treatment could successfully reduce acute postoperative pain and improve the course of physical and psychological recovery of people undergoing open heart surgery. We found 19 studies including a total of 2164 participants which reported effects of psychological treatment compared to a control group on pain intensity, use of pain medication, mental distress, mobility and duration of intubation after surgery. We did not find evidence that psychological treatment reduces pain intensity or enhances mobility after open heart surgery. Psychological treatment proved to be slightly better than standard care in reducing mental distress. We did not find clear evidence that psychological treatment leads to a reduced intubation time after surgery. No adverse effect of psychological treatment was described in any primary study.

However, studies were of low quality in general, and there was also variation between the results of studies. The latest search was conducted in September 2013. Studies were mostly conducted without external financial support or funded by non-commercial national or regional research associations or student fellowships. Conflicts of interest were not stated in any study.

Further research of high quality is required to answer the question of whether psychological treatment has the potential to reduce postoperative pain and improve recovery after open heart surgery.

## SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [\[Explanation\]](#)

Psychological interventions compared with control conditions for acute pain after open heart surgery				
<b>Patient or population:</b> Adults undergoing open heart surgery <b>Settings:</b> inpatient, surgical care <b>Intervention:</b> psychological intervention <b>Comparison:</b> control condition (either standard care or attention)				
Outcomes	Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
<b>Pain intensity measured with continuous scales: medium-term</b> various self-report scales (follow-up: 24 hours postoperatively to discharge)	g -0.02 (-0.24 to 0.20)	413 (4 studies)	⊕⊕⊕○ <b>moderate</b>	No beneficial effects of psychological interventions in reducing pain intensity
<b>Pain intensity measured with continuous scales: long-term</b> various self-report scales (follow-up: after discharge up to 4 weeks after discharge)	g 0.12 (-0.09 to 0.33)	280 (3 studies)	⊕⊕○○ <b>low</b>	No beneficial effects of psychological interventions in reducing pain intensity
<b>Mental distress: medium-term</b> various self-reported scales (follow-up: 1 day postoperatively to discharge)	g 0.36 (0.10 to 0.62)	1144 (12 studies)	⊕⊕○○ <b>low</b>	Intervention group participants reported less mental distress
<b>Mental distress: long-term</b> various self-reported scales (follow-up: after discharge up to 24 months after discharge)	g 0.28 (0.05 to 0.51)	1320 (11 studies)	⊕⊕○○ <b>low</b>	Intervention group participants reported less mental distress
<b>Mobility: medium-term</b> Jenkins Activity Checklist, Sickness Impact Profile, Integrated Motor Activity Monitor (follow-up: 2 postoperative days to discharge)	g 0.23 (-0.22 to 0.67)	444 (3 studies)	⊕⊕○○ <b>low</b>	No beneficial effects of psychological interventions in enhancing post-operative mobility

<b>Mobility: long-term</b> Jenkins Activity Check-list, Sickness Impact Profile, Nottingham Health Profile (follow-up: after discharge up to 24 weeks after discharge)	g 0.29 (-0.14 to 0.71)	423 (4 studies)	⊕⊕○○ <b>low</b>	No beneficial effects of psychological interventions in enhancing post-operative mobility
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CI: Confidence interval; g: Hedge's g

GRADE Working Group grades of evidence

**High quality:** Further research is very unlikely to change our confidence in the estimate of effect.

**Moderate quality:** Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

**Low quality:** Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

**Very low quality:** We are very uncertain about the estimate.

Reasons for downgrading the evidence are listed in the [Quality of the evidence](#) section.

## BACKGROUND

### Description of the condition

Open heart surgery is one of the most frequently conducted major surgical procedures in general hospitals. About 400,000 coronary artery bypass graft surgeries (CABG) and 100,000 valve surgeries were performed in the United States in 2007 (Roger 2011). In Germany, about 40,000 CABG procedures and about 25,000 valve surgeries were registered in 2010 (Gummert 2011).

The most disturbing complaint in open heart surgery is acute pain, which is still a severe and undertreated problem (Cogan 2010). Acute pain is the most common patient complaint after open heart surgery, and pain relief is often perceived as inadequate during the hospital recovery period (Aslan 2009; Valdix 1995).

The worst pain is experienced during the first 48 hours which are spent in the intensive care unit (ICU). Following intensive care, the presence of chest tubes and their removal, endotracheal tube suctioning, vomiting, turning, breathing and change of dressing are also severely painful experiences (Aslan 2009; Gelinas 2007). Pain symptoms after open heart surgery can be multiple, are described as burning or throbbing, located mainly in the thorax at the site of sternal incision, and may be of visceral, musculoskeletal or neurogenic origin (Cogan 2010; Gelinas 2007).

Acute postoperative pain has negative consequences for health. It has been shown that people undergoing cardiac surgery with severe levels of acute postoperative pain have a 3.5 times higher risk of suffering from chronic pain after cardiac surgery (Cogan 2010). Evidence also demonstrates that postoperative pain is a significant predictor of postoperative wound healing (McGuire 2006), a key variable of postoperative recovery in open heart surgery. Moreover, poor pain management may lead to depression (Cogan 2010) in addition to negative pulmonary, cardiac, gastrointestinal and musculoskeletal effects. There is clear evidence that post-CABG depression predicts decreased health-related quality of life, reduced activity levels, chronic chest pain, poorer cardiac symptom relief, as well as increased rates of rehospitalisation and mortality independent of cardiac status, somatic comorbidity or the extent of surgery (Barth 2004; Blumenthal 2003; Burg 2003; Connerney 2001; Doering 2005; Goyal 2005; Mallik 2005; Oxlad 2006; Pignay-Demaria 2003). However, to our knowledge there are no empirical studies which test the pathways between acute postoperative pain after CABG, post-CABG depression and worse surgical long-term outcomes in one model. Thus, the underlying mechanisms as yet remain unclear.

It is not surprising that acute postoperative pain after open heart surgery is mainly determined by surgery-related factors (e.g. duration and the location of surgery; Sommer 2008). However, given

the association between anxiety, depression and postoperative outcomes such as mortality, wound healing and complications (Ai 2006; Connerney 2001; Ho 2005; Mavros 2011; Perski 1998; Stengrevics 1996; Szekely 2007; Tully 2008), research has investigated the question of whether the psychological condition of patients influences postoperative pain levels after open heart surgery. Consequently, attempts have been made to determine if psychological interventions can successfully reduce acute postoperative pain and improve the course of physical and psychological recovery of people undergoing open heart surgery.

## Description of the intervention

This review focuses on psychological interventions, defined as those based on established psychological theories of behaviour and behaviour change, with identifiable components of treatment, specifically designed to alter surgery-related mental distress, negative beliefs and non-compliance in order to improve the postoperative recovery after open heart surgery. Psychological interventions in the context of cardiac surgery are conducted as an adjunct to standard surgical care within the time of hospitalisation by physicians, psychologists, nurses or other trained treatment providers (e.g. former patient models), including personal communication, printed information (leaflets), or audio or video recordings (Tigges-Limmer 2011). The following types of psychological intervention are common in the context of cardiac surgery: *Psychoeducational interventions*, which are defined as the provision of information about pre-, intra- and postoperative medical procedures with a special focus on associated psychological responses, sensations and emotions. These interventions also involve behavioural instructions about appropriate ways people can adhere to medical advice to support their recovery (Devine 1992). *Cognitive-behavioural methods*, comprising methods of cognitive restructuring, reframing and reappraisal based on the evaluation of patients' specific needs according to their individual situation (Powell 2010).

*Relaxation techniques* are described as teaching or instructing patients systematically in, for example, progressive muscle relaxation, relaxing breathing techniques, (self) hypnosis, guided imagery or autogenic training (Green 2005; Michie 2008).

These interventions can partially overlap with other kinds of interventions, such as those that focus on psychological preparation of adults undergoing surgery under general anaesthesia, which will be covered by a forthcoming Cochrane review (Powell 2010). Moreover, the analgesic effects of clinical hypnosis will be the focus of another Cochrane review also considering the context of medical procedures (Hallquist 2013).

## How the intervention might work

There is no evidence-based model for how psychological interventions in the context of cardiac surgery might reduce postoperative pain. However, it is reasonable to assume that psychological interventions might reduce pain by the alteration of surgery-related mental distress, negative beliefs and non-compliance, as well as by their interactions with each other.

Psychological interventions focus on the reduction of anxiety, depression and mental distress, which in consequence might affect pain. There is evidence that negative emotions decrease the pain perception threshold (Rainville 2005). In studies on non-cardiac surgical patients levels of anxiety and depression predicted postoperative pain (Arpino 2004; Granot 2005; Johnston 1988; Linn 1988; Mathews 1981; Munafò 2001). In addition, in studies on people undergoing cardiac surgery it was demonstrated that psychosocial variables such as anxiety, depression and perceived social support are also associated with postoperative pain (Con 1999; Jette 1996; Karlsson 1999; Morone 2010).

Psychological interventions also deal with non-compliance to alter patients' behaviour. People undergoing open heart surgery are less likely to remain passive in their course of recovery if they are informed about the importance of compliance with early postoperative mobilisation and thereby might have a decreased rate of postoperative complications and lower levels of postoperative pain.

Cognitive interventions focus primarily on changing negative or dysfunctional beliefs and attitudes towards surgery into more positive and helpful ones. For example, a positive and confident attitude towards surgery and the recovery period is associated with reduced anxiety, facilitates postoperative behavioural activation and thereby might decrease pain levels (Heye 2002).

## Why it is important to do this review

Clinical trials have investigated whether psychological interventions were successful in reducing acute postoperative pain levels and in enhancing physical and psychological postoperative recovery after open heart surgery. However, no comprehensive systematic review or meta-analysis of this evidence has been carried out so far.

## OBJECTIVES

To compare the efficacy of psychological interventions as an adjunct to standard care versus standard care alone or standard care plus attention in adults undergoing open heart surgery on pain, pain medication, mental distress, mobility, and time to extubation.

## METHODS



## Criteria for considering studies for this review

### Types of studies

We included randomised controlled trials (RCTs) irrespective of language, publication date or publication status. We limit inclusion to studies with a sample size of at least 20 participants in each trial arm at first postoperative assessment (Moore 2010; Eccleston 2012).

### Types of participants

We considered as eligible for inclusion all adult participants (men and women aged 18 and over) undergoing open heart surgery (valve procedures with or without cardiopulmonary bypass (CPB), coronary surgery with or without CPB, congenital lesion, surgery of thoracic aorta, other cardiac surgery, e.g. resection of heart neoplasm and assist devices). We excluded studies on emergency procedures and heart transplantation because patients differ in disease severity and time to be psychologically prepared for surgery, among other factors. We included participants independent of their pre- and postoperative mental health status.

### Types of interventions

#### Experimental intervention

As described above (see 'Description of the intervention' section) we focused on the following types of psychological interventions provided within the time of hospitalisation:

- Psychoeducational interventions;
- Cognitive-behavioural methods;
- Relaxation techniques.

We included studies in which intervention group participants received at least one of the interventions described above.

We excluded studies in which intervention group participants received a combination of a psychological intervention and a non-psychological intervention.

Studies which focused on life-style changes, pharmacological or psychotherapeutic long-term treatment after discharge of high-risk cardiac surgery patients with an a priori or a posterior diagnosis of major depression or anxiety disorder were not in the scope of our review. Long-term psychological interventions included in cardiac rehabilitation programmes have been covered by another Cochrane review (Whalley 2011).

We excluded music interventions, as pain, distress and anxiety-reducing effects of music in various cardiac patient populations have already been addressed in a recent Cochrane review (Bradt 2013).

#### Comparator intervention

- 'treatment as usual' (TAU), defined as the standard care of the hospital with no psychological intervention provided to the control group;

- 'attention control', defined as providing the same amount of time and attention, but with no specific psychological intervention offered to the control group.

### Types of outcome measures

We reported postoperative outcomes according to the following time intervals:

- 1st interval - short-term effects: outcome measures within the first 48 hours postoperatively.
- 2nd interval - medium-term effects: measures that took place after the first postoperative 48 hours and before discharge.
- 3rd interval - long-term effects: outcome measures after discharge.

#### Primary outcomes

1. Number of participants with self-reported pain intensity reduction of at least 50% from baseline.
2. Number of participants below 30/100 mm on the visual analogue scale (VAS) in self-reported postoperative pain intensity.
3. Participant-reported postoperative pain intensity measured on continuous or categorical scales, or other patient-reported pain intensity scales or questionnaires with satisfactory reliability and validity.

#### Secondary outcomes

1. Observer-reported postoperative median time to remedication.
2. Observer-reported postoperative number of participants remedicated.
3. Observer-reported postoperative analgesic use measured via patient-controlled analgesia (PCA), which will be converted into morphine equivalents.
4. Participant-reported postoperative mental distress (defined as negative affect, anxiety, depression, mood, well-being, relaxation) measured via:
  - i) visual analogue scales (VAS), numerical rating scales (NRS), verbal rating scales (VRS);
  - ii) Profile of Mood Scale (POMS, McNair 1971);
  - iii) Brief Symptom Inventory (BSI, Derogatis 1983);
  - iv) State Anxiety form of State-Trait-Anxiety-Inventory (STAI-S, Spielberger 1983);
  - v) Hospital Anxiety and Depression Scale (HADS, Zigmond 1983);
  - vi) Other patient-reported psychological distress rating scales with satisfactory reliability and validity.

5. Participant- and observer-reported postoperative levels of mobility measured via, for example, the six-minute walk test (Guyatt 1985).

6. Observer-reported time to extubation.

We preferred dichotomous outcomes if studies reported both continuous and dichotomous outcomes on pain intensity or analgesic use.

We reported the incidence of postoperative complications; however, we did not run meta-analytic procedures for this outcome as pooling of various postoperative complications with different severity levels leads to pooled heterogeneous estimates with no clear interpretation. Postoperative complications were defined as common consequences or events that are associated with the surgical procedure adversely affecting the patient's prognosis (Jacobs 2007; Rosendahl 2009): myocardial infarction, reoperation, cardiac arrest, prolonged ventilation (> 24 hours), rethoracotomy, wound infection, renal failure, pneumothorax, pericardial effusion, pleural effusion, arrhythmia and transient delirium.

## Search methods for identification of studies

### Electronic searches

We carried out electronic searches for this review in the following databases:

- CENTRAL (*The Cochrane Library*, all years to 2013, Issue 8)
- MEDLINE (1946 to September 2013)
- EMBASE (1980 to September 2013)
- Web of Science (all years to September 2013)
- PsycINFO (all years to September 2013)
- ProQuest Dissertations and Theses Full Text Database (all years to September 2013)

A MEDLINE search strategy, based on both indexed and free-text terms and incorporating the Cochrane Highly Sensitive Search Strategy for identifying randomised controlled trials, is shown in [Appendix 1](#). We adapted the strategy for the Cochrane Central Register of Controlled Trials (CENTRAL, [Appendix 2](#)), and EMBASE database ([Appendix 3](#)) as well as for PsycINFO ([Appendix 4](#)) and Web of Science ([Appendix 5](#)). We used the 'related articles' and 'cited by' options of eligible studies to identify additional relevant studies.

### Searching other resources

We checked lists of references of relevant articles and previous reviews in order to identify eligible studies. Additionally, we searched the ProQuest Dissertations and Theses Full Text Database (all years to September 2013) and contacted the authors of primary studies to identify any unpublished material.

## Data collection and analysis

### Selection of studies

Two review authors (SK and JR) independently screened titles and abstracts of retrieved articles for eligibility.

### Data extraction and management

Two review authors (SK and JR) extracted data independently using a pilot-tested electronic data extraction form. We resolved disagreements through discussion and consultation with a third review author (JB). In order to obtain missing information, we contacted study authors for clarification.

We extracted the following information from primary studies:

- Information on publication (title, authors, year, publication status, language, country).
- Population (clinical participant characteristics, sample size, age, gender).
- Intervention type.
- Control group type.
- Outcomes (time interval of measurement, effect size-related parameters (including frequencies, change scores, means, standard deviations, *t* or *F* values, and probability levels)).

### Assessment of risk of bias in included studies

Two review authors (SK and JR) independently assessed the risk of bias for each included study using the Cochrane 'Risk of bias' tool (Higgins 2011a). We assessed the risk of selection bias (random sequence generation, allocation concealment), the risk of attrition bias (incomplete outcome data) and the risk of reporting bias (selective reporting). As blinding of participants and therapists is not possible in psychological intervention research, we assessed the risk of performance bias by evaluating the blinding status of medical personnel only. Medical personnel were defined as care providers (physicians, surgeons, nurses) who were not involved in the provision of adjunctive psychological interventions. We assessed the risk of detection bias (blinded outcome assessment) for observer-reported outcomes and for participant-reported outcomes separately. We used a consensus method to resolve disagreements.

### Measures of treatment effect

We used the risk ratio (RR) as a measure of treatment effect for all dichotomous outcomes. Additionally, we calculated the number needed to treat for an additional beneficial outcome (NNTB) for dichotomous outcomes. We used Hedges' adjusted *g* for all continuous outcomes. Hedges' *g* is similar to Cohen's well-known effect size *d* but includes an adjustment to correct for small sample size. It was calculated by dividing the differences in mean values

with the pooled standard deviation (Cohen's effect size) multiplied by a small sample size correction factor (Hedges 1981). Effect sizes of those multi-arm studies with similar psychoeducation intervention groups and a shared control group (Anderson 1987; Mahler 1998; Mahler 1999) or of studies with a shared intervention group and two different control groups (Pick 1994) are stochastically dependent. We therefore used recommended procedures to account for the correlations among the within-study outcome measures related to multiple comparisons (Gleser 2009; Higgins 2011b). We calculated a weighted average of the pair-wise comparisons and a variance taking into account the correlation between comparisons (Higgins 2011b). The correlation between within-study effect sizes was set at 0.50 (Wampold 1997). Within-study aggregation of effect sizes was done by using the *R* package MAd (Del Re 2010).

With regard to the continuous primary outcome (self-reported postoperative pain intensity), we prespecified a minimal clinically relevant group mean difference of  $g = 0.4$ , corresponding to 10 mm on a 100 mm visual analogue scale (VAS). This difference has been found to be clinically relevant in a randomised controlled study examining effects of relaxation on postoperative pain (Good 1999), since it has been associated with significantly reduced distress and also with reduced heart and respiratory rates moderating sympathetic nervous system activity.

### Unit of analysis issues

We measured all outcomes at the participant level.

### Dealing with missing data

Whenever possible we used results from an intention-to-treat (ITT) analysis. If outcome data for dichotomous outcomes were incompletely reported (e.g. the analysis set was smaller than the number of participants randomised) we used the reported analysis population. If standard deviations (SDs) were not provided for continuous outcomes, we calculated them from standard errors or confidence intervals (CI) as described elsewhere (Reichenbach 2007).

### Assessment of heterogeneity

We quantified heterogeneity using the  $I^2$  statistic and  $\text{Tau}^2$  (Higgins 2002). We estimated  $\text{Tau}^2$  using the DerSimonian-Laird method (DerSimonian 1986). We assessed any heterogeneity in subgroup analyses and sensitivity analyses as described below.

### Assessment of reporting biases

We assessed reporting biases and small study effects visually in funnel plots and formally as described previously (Sterne 2011).

### Data synthesis

We meta-analysed outcome data using a random-effects approach. We used the generic inverse variance method with heterogeneity estimated using the DerSimonian-Laird method (DerSimonian 1986).

Many studies used different outcome measures as endpoints. These outcome measures represented different outcome constructs (e.g. pain, mobility, anxiety, depression). Our approach was to define reasonable sets of outcome categories that included different operationalizations but distinguished different content domains of interest (Gleser 2009). Our outcome categories of interest are described in the Methods section (Types of outcome measures). For example, data for the outcome constructs of anxiety, depression, mood, well-being, negative affect, and relaxation, were pooled within the outcome category 'mental distress' across studies. Pooling data from independent participants across studies introduced no bias, because the studies, and the effect sizes, were statistically independent.

We calculated a treatment versus control effect-size for each outcome measure (Measures of treatment effect). Subsequently, we pooled these effects by computing the mean (and its variance) of the effect sizes (Borenstein 2009) from different outcome constructs within an outcome category study. This synthetic summary effect was used as the unit of analysis in the meta-analysis. We only combined outcomes which were measured with the same metric and used the smaller  $N$  under the assumption that patients with missing scores on one of the outcome measures had the same mean score on the other outcome measure.

We chose this form of averaging effects because we were interested in a broad range of study results and welcomed diverse measures and constructs. We wanted to use as much information as possible for effect estimation and avoid information loss, hence we decided against a rule for hierarchical outcome data extraction.

Some of the included trials had a more complex data structure and provided multiple measures as endpoints for each subject (*multiple-endpoint studies*, Gleser 2009). In these studies we also computed a treatment versus control effect-size for each endpoint measure (Measures of treatment effect). However, pooling multiple measures from the same participants within studies introduces bias due to statistical dependency in the data, because multiple measures on the same participants are correlated, so are corresponding effect-sizes. Statistically dependent data are related to a number of problems, e.g. combining statistical dependent effect sizes leads to an improper estimate of the precision of the synthetic summary effect since the standard error for the synthetic summary effect will likely be erroneously small, study weightings will be spuriously precise, the confidence interval too narrow, and statistical significance tests likely to reject more often than the nominal significance level (Borenstein 2009).

Those statistically dependent effect-sizes cannot be included in one analysis unless special adjustments are made. Therefore, we followed the recommendation of Gleser 2009 and Borenstein 2009

to overcome those problems which have important implications for the validity of the results of the meta-analysis.

In order to avoid fundamental problems related to a dependent data structure, we controlled for these dependencies among the estimated effect sizes in the analysis and estimated the between-measures correlations to be  $r = 0.50$  as has been suggested by [Wampold 1997](#). We used the formulas for the correlations provided by [Gleser 2009](#) and computed the pooled effect sizes with the statistical R package MAd ([Del Re 2010](#)). The MAd aggregation function implements the [Gleser 2009](#) procedures for aggregating dependent effect sizes. By applying these procedures, the estimated effects did not suffer from an improper estimate of the precision.

Some studies reported results on the same variables measured at different times. These outcome measures represented measures of the same construct at different time points (e.g. depression at first postoperative day and depression at second postoperative day).

Again, our approach was to use all available information for effect estimation. We therefore considered all time points worth analyzing in order to depict the course of postoperative pain and other outcome categories. We followed the recommendation by [Gleser 2009](#) and established broad categories for time intervals and coded each result in the time interval it fitted most closely. In particular, we were interested in short-, medium- and long-term effects of psychological interventions. These time intervals are described in the Methods section ([Types of outcome measures](#)).

If studies reported results for different time points (within the same time interval) we combined those effect sizes to an average effect estimation representing the treatment effect for this specific time interval. As has been described above, if data from independent participants were pooled across studies no bias was introduced.

However, if data at different time points (within the same time interval) came from the same participants within a given study, we again applied the procedures described above to account for statistical dependency in the data.

### Subgroup analysis and investigation of heterogeneity

To identify sources of heterogeneity, we conducted subgroup analyses according to different intervention types and control group types ([Harbord 2008](#); [Thompson 2002](#)).

### Sensitivity analysis

We carried out sensitivity analyses to explore the influence of risk-of-bias components on effect size estimation ([Juni 2001](#)). We tested the robustness of effects against the exclusion of effect sizes being approximated due to missing statistical parameters in primary studies. Accordingly, we carried out a sensitivity analysis with regard to studies with reliable effect estimates from means, standard deviations and sample sizes.

## RESULTS

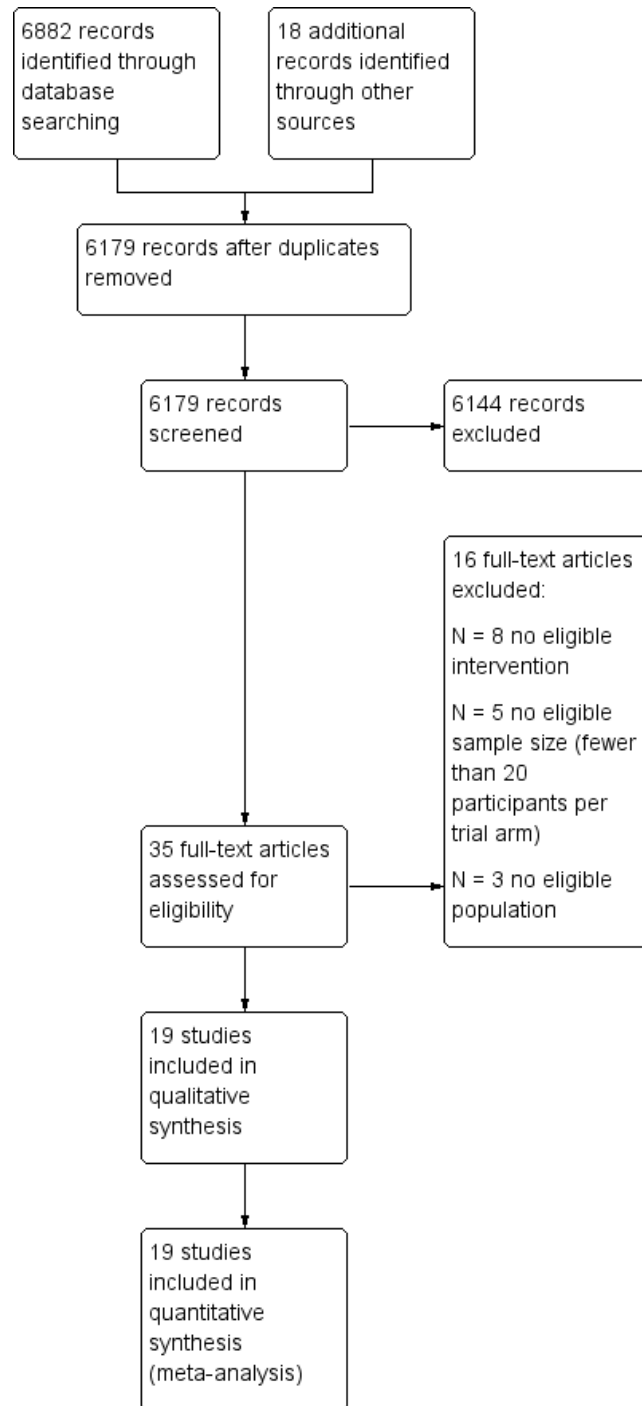
### Description of studies

See: [Characteristics of included studies](#) and [Characteristics of excluded studies](#)

### Results of the search

We identified 35 studies as potentially eligible after screening for inclusion and exclusion criteria. We included a total of 19 studies in this review ([Characteristics of included studies](#)); we excluded 16 studies ([Characteristics of excluded studies](#)). [Figure 1](#) illustrates the process of screening and selecting studies for inclusion in this review.

**Figure 1. Study flow diagram.**



## Included studies

We included 19 randomised controlled clinical trials. Of these, five were from the USA (Anderson 1987; Gilliss 1993; Mahler 1998; Mahler 1999; Moore 2001) and another four were conducted in Europe (Austria: Bergmann 2001; Germany: Parthum 2006; UK: Pick 1994; Norway: Sørli 2007). Two studies were from Canada (Martorella 2012; Parent 2000) and from Iran (Heidarnia 2005; Zarani 2010). One trial each was from Australia (Shelley 2007), China (Guo 2012), Lebanon (Deyirmenjian 2006), South Africa (De Klerk 2004), Taiwan (Ku 2002) and Thailand (Utriyaprasit 2010). All of the 19 included trials were published within the last two decades, with the earliest in 1987 (Anderson 1987) and the latest in 2012 (Guo 2012). All studies were published in English except one trial, (Parthum 2006), which was published in German. All of the 19 included studies were available as published papers. We were not able to identify any additional unpublished or ongoing studies through a search in the ProQuest Dissertation and Thesis Database or by contacting primary study authors.

Overall, the 19 trials reported data from 2164 participants (1171 with a psychological intervention; 993 in a control condition). The mean age of intervention group participants was from 52 to 68 years, similar to the range of mean age in control group participants (52 to 69). The unweighted mean prevalence of male participants in the intervention groups (81.5%) and control groups (81.0 %) was also comparable.

## Types of interventions

We looked at three different types of psychological interventions provided within the time of hospitalisation (psychoeducation, cognitive-behavioural methods, relaxation). In the majority of studies participants received a single type of intervention: most often psychoeducation was implemented (Anderson 1987; Bergmann 2001; Deyirmenjian 2006; Guo 2012; Ku 2002; Mahler 1998; Mahler 1999; Martorella 2012; Moore 2001; Parent 2000; Parthum 2006). Two trials applied relaxation (De Klerk 2004; Pick 1994), but no trial provided cognitive-behavioural methods exclusively. Six studies applied two types of interventions: five combined psychoeducation with cognitive-behavioural methods (Gilliss 1993; Heidarnia 2005; Shelley 2007; Sørli 2007; Zarani 2010), and in one trial a combination of psychoeducation and relaxation was implemented (Utriyaprasit 2010).

Intervention sessions lasted from at least 15 minutes (Moore 2001) up to 120 minutes and longer (De Klerk 2004), but with relevant data often not reported in detail. The majority of studies implemented preoperative interventions (Anderson 1987; Bergmann 2001; Deyirmenjian 2006; Guo 2012; Heidarnia 2005; Ku 2002; Mahler 1998; Mahler 1999; Parthum 2006; Shelley 2007; Zarani

2010), while Gilliss 1993; Moore 2001; Utriyaprasit 2010 applied interventions postoperatively. Five trials considered both pre- and postoperative interventions (De Klerk 2004; Martorella 2012; Parent 2000; Pick 1994; Sørli 2007).

In five trials specialist nurses provided the interventions (Gilliss 1993; Guo 2012; Mahler 1998; Mahler 1999; Sørli 2007), while in one trial a surgeon conducted the intervention (Bergmann 2001). Both, researchers (De Klerk 2004; Ku 2002; Martorella 2012; Pick 1994; Shelley 2007) and former patients (Mahler 1998; Mahler 1999; Parent 2000) provided interventions as well. Only two trials reported that intervention providers received special training (Parent 2000; Sørli 2007), while others explicitly stated that there had not been any coaching of intervention providers (Bergmann 2001; Mahler 1998; Mahler 1999). Six trials referred to a special programme, manual or model (Heidarnia 2005; Ku 2002; Martorella 2012; Moore 2001; Utriyaprasit 2010; Zarani 2010).

The intervention format differed across trials. Slide-tape and telephone contacts (Gilliss 1993), as well as audio-tapes (Anderson 1987; De Klerk 2004; Moore 2001; Pick 1994; Utriyaprasit 2010) and video-tapes (Anderson 1987; Mahler 1998; Mahler 1999; Sørli 2007; Zarani 2010) were used as formats to implement the intervention content. One of the recent studies used an innovative web application approach (Martorella 2012). However, the majority of trials implemented the intervention (additionally) via a face-to-face contact (Bergmann 2001; De Klerk 2004; Deyirmenjian 2006; Gilliss 1993; Guo 2012; Heidarnia 2005; Ku 2002; Martorella 2012; Parent 2000; Parthum 2006; Pick 1994; Shelley 2007; Sørli 2007; Zarani 2010). Brochures were also common (Guo 2012; Heidarnia 2005; Ku 2002; Parthum 2006; Zarani 2010). Two trials used a group setting for intervention implementation (Heidarnia 2005; Zarani 2010). More than half of the studies combined at least two types of intervention formats. Most commonly a face-to-face contact was combined with a brochure (Guo 2012; Heidarnia 2005; Ku 2002; Parthum 2006; Zarani 2010) or an audio- (De Klerk 2004; Pick 1994) or video-tape (Sørli 2007; Zarani 2010). One study (Anderson 1987) combined audio-tape, video-tape, and face-to-face contact.

## Types of comparators

Most trials used TAU (treatment as usual) control groups (Bergmann 2001; De Klerk 2004; Deyirmenjian 2006; Gilliss 1993; Guo 2012; Heidarnia 2005; Mahler 1998; Mahler 1999; Martorella 2012; Moore 2001; Parent 2000; Parthum 2006; Shelley 2007; Sørli 2007). Four studies referred to attention control groups exclusively (Anderson 1987; Ku 2002; Utriyaprasit 2010; Zarani 2010), while Pick 1994 comprised both a TAU control and an attention control group. Apart from three trials with



three treatment arms (Anderson 1987; Mahler 1999; Pick 1994) and one study with four treatment arms (Mahler 1998), all other studies comprised two treatment arms.

Two attention control groups used emotional support (Pick 1994) and supportive counselling (Zarani 2010), while participants in a further three attention control groups received cardiac teaching combined with discharge instructions (Utriyaprasit 2010) or preoperative nursing care combined with a 10-minute social visit daily during hospitalisation (Ku 2002), or an interview focusing on neutral hospital-related topics (Anderson 1987).

## Types of outcomes

### Primary outcome

The primary outcome of participant-reported pain intensity was assessed in six trials (the number of participants below 30/100 mm on the VAS by Parthum 2006; and pain intensity on continuous scales by Guo 2012; Heidarnia 2005; Martorella 2012; Shelley 2007; Utriyaprasit 2010). One of the primary outcomes (number of participants with self-reported pain intensity reduction of at least 50% from baseline) was not reported in any of the included trials.

### Secondary outcomes

We were unable to extract either the postoperative median time to remedication, or the number of participants remedicated. The most frequently assessed outcome was postoperative mental distress. Participant-reported levels of postoperative mental distress were measured with the Hospital Anxiety and Depression Scale (Guo 2012; Martorella 2012; Zarani 2010), the Profile of Mood Scale (De Klerk 2004; Gilliss 1993; Moore 2001; Utriyaprasit 2010) and the State-Trait-Anxiety-Inventory (Anderson 1987; Bergmann 2001; Ku 2002; Parent 2000). However, the majority of studies used other psychological distress rating scales (Anderson 1987; Bergmann 2001; De Klerk 2004; Deyirmenjian 2006; Heidarnia 2005; Mahler 1999; Pick 1994; Shelley 2007; Sørle 2007).

The observer-reported time to extubation (Deyirmenjian 2006) as well as the observer-reported postoperative analgesic use measured via patient-controlled analgesia (PCA) (Martorella 2012)

were extracted from one trial each. Five studies measured self- and observer-reported postoperative levels of mobility (Gilliss 1993; Heidarnia 2005; Mahler 1998; Parent 2000; Utriyaprasit 2010). Three studies reported postoperative complications (Deyirmenjian 2006; Martorella 2012; Parent 2000, see Table 1). We reported outcome measures according to the three time intervals: short-term effects (within the first 48 hours postoperatively), medium-term (after the first postoperative 48 hours and before discharge), and long-term (outcome measures after discharge). Only four trials assessed short-term intervention effects (Deyirmenjian 2006; Martorella 2012; Parthum 2006; Pick 1994). More often the outcome measurements took place after the first postoperative 48 hours and before discharge (Anderson 1987; Bergmann 2001; De Klerk 2004; Deyirmenjian 2006; Guo 2012; Ku 2002; Mahler 1998; Mahler 1999; Martorella 2012; Shelley 2007; Sørle 2007; Utriyaprasit 2010), or after discharge of the participants (De Klerk 2004; Gilliss 1993; Heidarnia 2005; Mahler 1999; Parent 2000; Pick 1994; Shelley 2007; Sørle 2007; Utriyaprasit 2010; Zarani 2010 Moore 2001). While the earliest postoperative measure took place after awaking from anaesthesia (Deyirmenjian 2006), the longest follow-up assessment was conducted two years after discharge (Sørle 2007).

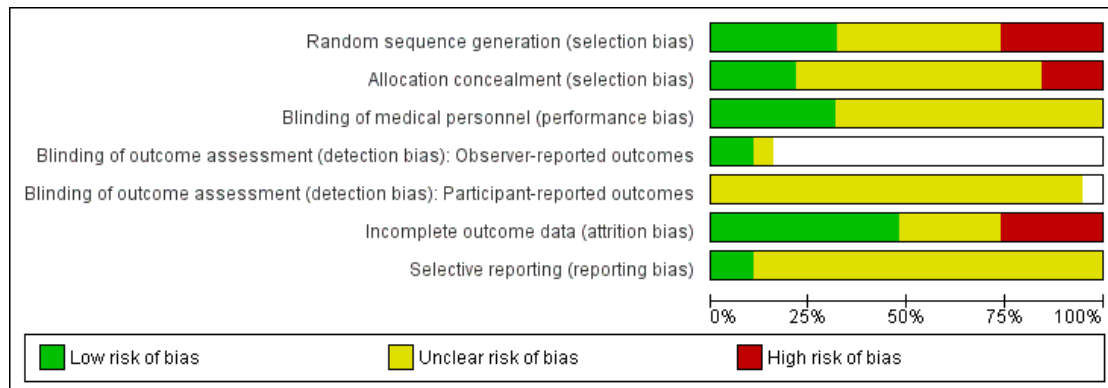
### Excluded studies

We excluded 16 studies (See [Characteristics of excluded studies](#)) due to the following reasons: intervention was provided before admission to hospital (Cupples 1991; Hermele 2005; Lamarche 1998; Shuldham 2002; Watt-Watson 2004); intervention was provided almost exclusively after discharge (Hartford 2002); intervention was not eligible for inclusion (Hemi-Sync tape, Ikedo 2007; similar-other support, Thoits 2000); people for nonelective open heart surgery were recruited (Blankfield 1995); people under 18 years of age were recruited (Hwang 1998); people undergoing open heart surgery were not recruited (Yin 2011); the sample size was fewer than 20 participants in each group at first postoperative assessment (Ashton 1997; Houston 1999; Postlethwaite 1986; Stein 2010; Watt-Watson 2000).

### Risk of bias in included studies

Figure 2 and Figure 3 depict a graphical representation of the 'Risk of bias' assessments.

**Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.**





**Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.**

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of medical personnel (performance bias)	Blinding of outcome assessment (detection bias): Observer-reported outcomes	Blinding of outcome assessment (detection bias): Participant-reported outcomes	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)
Anderson 1987	?	?	+		?	?	?
Bergmann 2001	?	?	?		?	+	?
De Klerk 2004	?	?	+		?	?	?
Deyirmenjian 2006	-	-	?	+	?	+	?
Gilliss 1993	+	+	?		?	+	?
Guo 2012	+	+	+		?	+	+
Heidarnia 2005	-	-	?		?	-	?
Ku 2002	-	?	?		?	?	?
Mahler 1998	?	?	?	?		?	?
Mahler 1999	?	?	?		?	-	?
Martorella 2012	+	+	+	+	?	+	+
Moore 2001	+	?	?		?	+	?
Parent 2000	+	?	?		?	-	?
Parthum 2006	-	-	?		?	+	?
Pick 1994	?	?	?		?	-	?
Shelley 2007	?	?	+		?	?	?
Sørlie 2007	-	+	+		?	+	?
Utriyaiprasit 2010	+	?	?		?	+	?
Zarani 2010	?	?	?		?	-	?

## Allocation

We classified six of the 19 randomised controlled trials as being at low risk of bias due to an adequate random sequence generation (Gilliss 1993; Guo 2012; Martorella 2012; Moore 2001; Parent 2000; Utriya-prasit 2010), whereas only four trials applied an appropriate method to conceal the random allocation sequence (Gilliss 1993; Guo 2012; Martorella 2012; Sørli 2007).

## Blinding

Six trials (Anderson 1987; De Klerk 2004; Guo 2012; Martorella 2012; Shelley 2007; Sørli 2007) used adequate methods to blind medical personnel (physicians, surgeons, nurses) to participants' group assignment and were rated as being at low risk of performance bias.

The majority of trials used self reports of pain intensity, mental distress and mobility as outcome measures (Anderson 1987; De Klerk 2004; Deyirmenjian 2006; Gilliss 1993; Guo 2012; Heidarnia 2005; Ku 2002; Mahler 1999; Martorella 2012; Moore 2001; Parent 2000; Parthum 2006; Pick 1994; Shelley 2007; Sørli 2007; Utriya-prasit 2010; Zarani 2010), and were judged to be at unclear risk of detection bias. In trials with observer-reported outcome measures, we rated one trial as being at unclear risk of detection bias (Mahler 1998) due to insufficient information related to blinding status of the outcome assessors. We judged two trials to be at low risk of detection bias since they used blinded outcome assessors for postoperative analgesic use (Martorella 2012) and time to extubation (Deyirmenjian 2006); however, both studies also included participant-reported outcomes and were judged to be at unclear risk of detection bias with regard to the participant-

reported outcome class (Figure 3).

## Incomplete outcome data

Nine trials used adequate methods of incomplete outcome data handling and were rated as being at low risk (Bergmann 2001; Deyirmenjian 2006; Gilliss 1993; Guo 2012; Martorella 2012; Moore 2001; Parthum 2006; Sørli 2007; Utriya-prasit 2010).

## Selective reporting

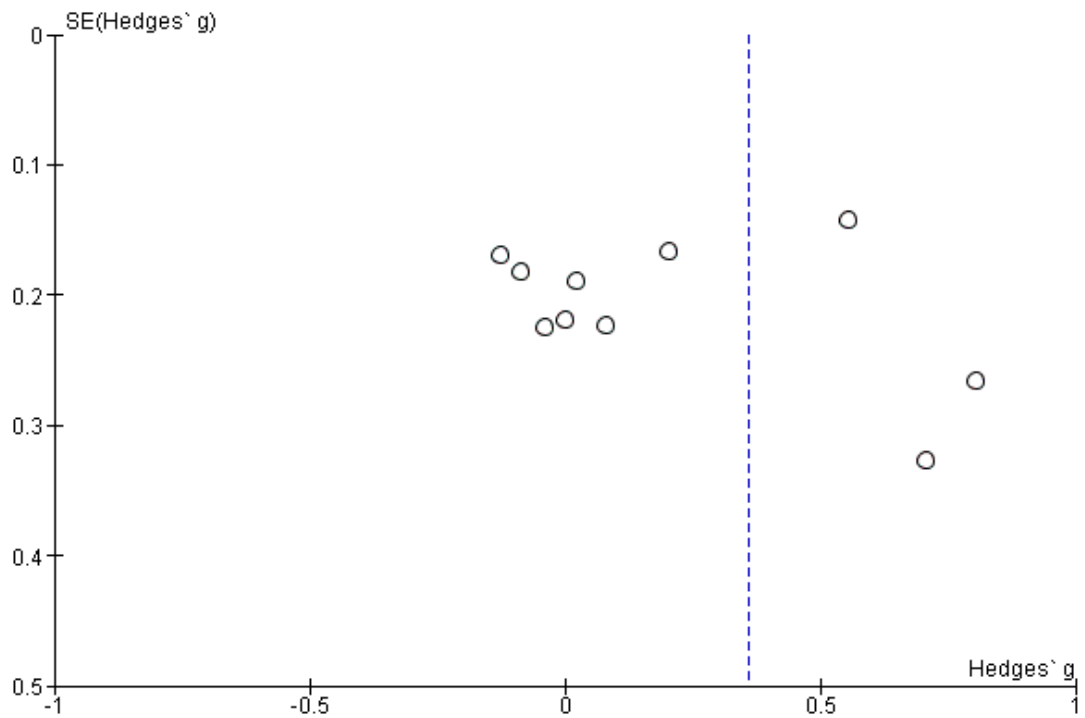
It has been suggested that definitive evidence that selective reporting has not occurred requires access to the study protocol that will have been published before the trial started (Higgins 2011a). However, only two study protocols were available (Guo 2012; Martorella 2012). For the remaining 17 studies we assumed an unclear risk of reporting bias.

## Other potential sources of bias

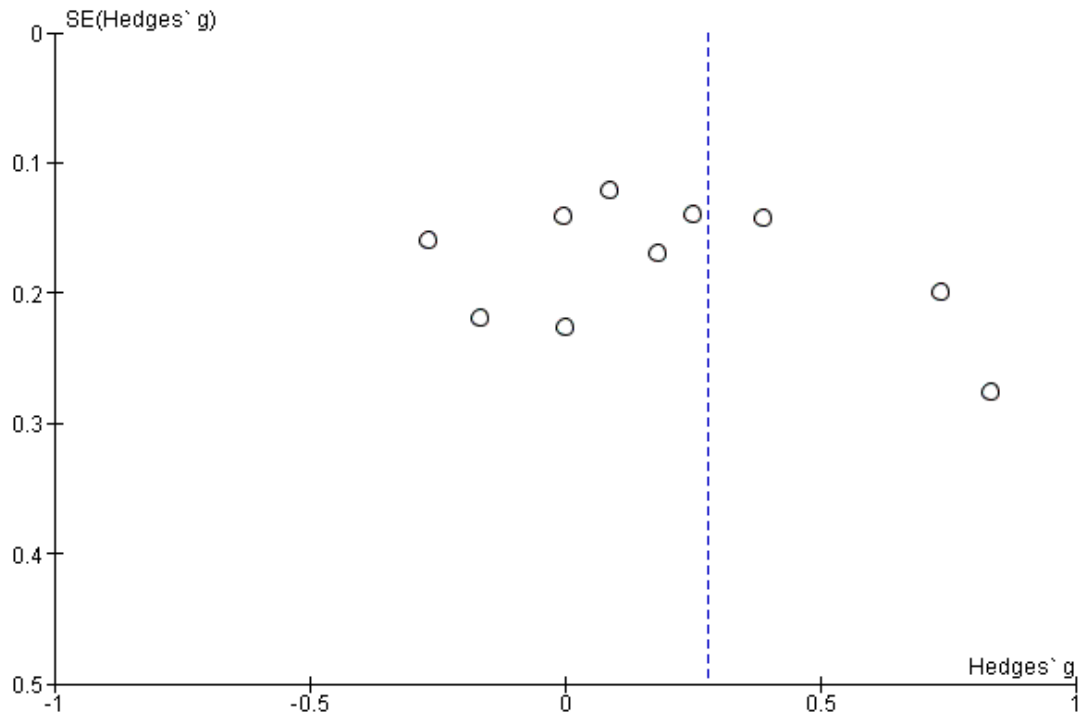
### Publication bias

Visually the funnel plots for the outcomes 'mental distress: medium-term' (Figure 4) and 'mental distress: long-term' (Figure 5) appeared not asymmetrical. We used the test proposed by Egger et al (Egger 1997) to formally test funnel plot asymmetry and obtained no significant evidence of small-study effects (medium-term:  $P = 0.143$ ; long-term:  $P = 0.139$ ). We did not use the Egger test for the other outcomes, because Sterne 2011 advises against the use of the test with substantially fewer than 10 studies.

**Figure 4. Funnel plot of comparison: I Psychological intervention vs control condition, outcome: I.3 Mental distress: medium-term.**



**Figure 5. Funnel plot of comparison: I Psychological intervention vs control condition, outcome: I.4 Mental distress: long-term.**



*from baseline.*

## Effects of interventions

See: [Summary of findings for the main comparison](#)

We reported results for all available outcome measures specified above.

### I Psychological intervention versus control condition

We included 19 trials (2164 participants) comparing psychological intervention against a control condition. In our meta-analyses the control condition was either standard care or attention, with one study including the comparison of a psychological intervention to both a standard care control group and an attention control group ([Pick 1994](#)).

#### *Number of participants below 30/100 mm on visual analogue scale (VAS) pain intensity*

Data on the number of participants below 30/100 mm on VAS pain intensity was only provided by one study (73 participants; [Parthum 2006](#)). There was no beneficial short-term effect of psychological intervention on pain intensity below 30/100 mm on the Visual Analogue Scale: risk ratio (RR) 1.20 (95% confidence interval (CI) 0.68 to 2.12). The number needed to treat for one additional beneficial outcome (NNTB) was 14 (95% CI -9 to 3).

### Primary outcome measures

*No study reported data on the number of participants with participant-reported pain intensity reduction of at least 50%*

#### *Pain intensity measured with continuous scales*

One study (60 participants, [Martorella 2012](#)) reported data on short-term effects of psychological intervention on pain intensity measured with continuous scales ( $g$  0.10, 95% CI -0.28 to 0.48) indicating no significant difference between the psychological intervention and control. Likewise, psychological interventions had

no beneficial medium-term effects ( $g$  -0.02, 95% CI -0.24 to 0.20,  $I^2 = 34\%$ , four studies, 413 participants, [Analysis 1.1](#)) or long-term effects ( $g$  0.12 95% CI -0.09 to 0.33,  $I^2 = 0\%$ , three studies, 280 participants, [Analysis 1.2](#)) on pain intensity measured with continuous scales.

Since we prespecified  $g$  0.4 as a minimal clinically relevant group mean difference, the identified effect sizes cannot be regarded as clinically relevant.

## Secondary outcome measures

No study reported data on observer-reported postoperative median time to remedication or observer-reported postoperative number of participants remedicated.

### Postoperative analgesic use

Only one trial (60 participants; [Martorella 2012](#)) provided data on postoperative analgesic use. Analgesic use within the first 48 hours after surgery (short-term interval) was small to moderate in effect size ( $g$  0.44, 95% CI 0.00 to 0.89) and of borderline significance. No difference in analgesic use was found after the first postoperative 48 hours and before discharge (medium-term interval) ( $g$  0.18, 95% CI -0.37 to 0.72). There were no long-term measures (post-discharge) for this outcome.

### Mental distress

Only one study ([Pick 1994](#); 74 participants) reported short-term data within the first 48 hours after surgery, and found no beneficial effect of psychological intervention ( $g$  0.00, 95% CI -0.44 to 0.44). We found small significant medium-term effects in favour of psychological intervention on mental distress after the first postoperative 48 hours and before discharge ( $g$  0.36, 95% CI 0.10 to 0.62,  $I^2 = 80\%$ , twelve studies, 1144 participants, [Analysis 1.3](#)) as well as small significant long-term effects after discharge ( $g$  0.28, 95% CI 0.05 to 0.51;  $I^2 = 80\%$ , eleven studies, 1320 participants, [Analysis 1.4](#)).

### Mobility

No study reported short-term effects on mobility. Psychological interventions had no beneficial medium-term effects ( $g$  0.23, 95% CI -0.22 to 0.67,  $I^2 = 80\%$ , three studies, 444 participants, [Analysis 1.5](#)) or long-term effects on mobility ( $g$  0.29, 95% CI -0.14 to 0.71,  $I^2 = 82\%$ , four studies, 423 participants, [Analysis 1.6](#)).

### Time to extubation

Data on time to extubation after surgery were provided by only one trial (110 participants; [Deyirmenjian 2006](#)), indicating a small short-term effect of borderline significance in favour of psychological intervention ( $g$  0.37, 95% CI 0.00 to 0.75).

## 2 Subgroup analysis: Psychological intervention versus standard care (TAU)

### Primary outcome measures

#### Number of participants below 30/100 mm on VAS pain intensity

Only one study reported data on the number of participants below 30/100 mm on VAS pain intensity (73 participants; [Parthum 2006](#)). There were no differences in the number of participants who reported a pain intensity below 30/100 mm on the VAS in the short-term interval (RR 1.20, 95% CI 0.68 to 2.12; number needed to treat for an additional beneficial outcome (NNTB) was 14, 95% CI -9 to 3).

#### Pain intensity measured with continuous scales

One study (60 participants, [Martorella 2012](#)) reported data on short-term effects of psychological intervention on pain intensity measured with continuous scales ( $g$  0.10, 95% CI -0.28 to 0.48) indicating no significant difference between the psychological intervention and standard care control group. Likewise, psychological interventions had no beneficial medium-term effects ( $g$  0.09, 95% CI -0.11 to 0.29,  $I^2 = 0\%$ , three studies, 293 participants, [Analysis 2.1](#)) or long-term effects ( $g$  0.18 95% CI -0.11 to 0.46,  $I^2 = 0\%$ , two studies, 160 participants, [Analysis 2.2](#)) on pain intensity measured with continuous scales compared to standard care (TAU). Since we prespecified  $g$  0.4 as a minimal clinically relevant group mean difference, the identified effect sizes cannot be regarded as clinically relevant.

### Secondary outcome measures

#### Postoperative analgesic use

Data on postoperative analgesic use was provided only in one trial (60 participants; [Martorella 2012](#)) reporting a small to moderate effect of borderline significance in favour of psychological intervention on short-term analgesic use within the first 48 hours after surgery ( $g$  0.44, 95% CI 0.00 to 0.89). The same study showed

no effect of psychological intervention compared to standard care control in analgesic use after the first postoperative 48 hours and before discharge (medium-term interval) (g 0.18, 95% CI -0.37 to 0.72).

### ***Mental distress***

Only one study (49 participants; [Pick 1994](#)) reported short-term data within the first 48 hours after surgery, with no difference between psychological intervention and standard care (g 0.00, 95% CI -0.44 to 0.44). After the first postoperative 48 hours and before discharge, small significant medium-term effects in favour of psychological intervention were found on mental distress (g 0.34, 95% CI 0.03 to 0.64;  $I^2 = 82\%$ , nine studies, 904 participants, [Analysis 2.3](#)) as well as small significant long-term effects after discharge (g 0.37, 95% CI 0.11 to 0.63;  $I^2 = 79\%$ , nine studies, 986 participants, [Analysis 2.4](#)).

### ***Mobility***

Studies showed no beneficial effects of psychological intervention compared to standard care on mobility in the medium-term interval (g 0.42, 95% CI -0.07 to 0.91,  $I^2 = 71\%$ , two studies, 324 participants, [Analysis 2.5](#)) as well as in the long-term interval (g 0.42, 95% CI -0.18 to 1.02,  $I^2 = 85\%$ , three studies, 303 participants, [Analysis 2.6](#)).

### ***Time to extubation***

Only one trial (110 participants; [Deyirmenjian 2006](#)) provided data on time to extubation after surgery in the short-term interval, indicating a small effect of borderline significance in favour of psychological intervention compared to standard care (g 0.37, 95% CI -0.00 to 0.75).

## **3 Subgroup analysis: Psychological intervention versus attention control group**

### **Primary outcome measures**

#### ***Pain intensity measured with continuous scales***

Pain intensity was reported in only one trial using a continuous scale (120 participants; [Utriyaaprasit 2010](#)) indicating no difference between psychological intervention and attention control group in the medium-term interval (g -0.33, 95% CI -0.69 to 0.03) as well as in the long-term interval (g 0.06, 95% CI -0.25 to 0.37).

## **Secondary outcome measures**

### ***Mental distress***

Only one study (50 participants; [Pick 1994](#)) reported short-term data within the first 48 hours after surgery, revealing no effect (g 0.00, 95% CI -0.44 to 0.44). We found no difference between psychological intervention and attention control group in medium-term (g 0.44, 95% CI -0.19 to 1.07;  $I^2 = 79\%$ , three studies, 240 participants, [Analysis 3.1](#)) and long-term effects (g -0.05, 95% CI -0.28 to 0.18;  $I^2 = 36\%$ , three studies, 350 participants, [Analysis 3.2](#)).

### ***Mobility***

Only one study measured mobility (120 participants; [Utriyaaprasit 2010](#)), showing no difference between psychological intervention and attention control group in the medium-term interval (g -0.13, 95% CI -0.44 to 0.18) as well as in the long-term interval (g -0.04, 95% CI -0.32 to 0.24).

## **4 Subgroup analysis: Psychoeducation versus control condition**

Studies comparing psychoeducation against a control condition revealed a small effect in favour of psychoeducation on mental distress in the medium-term interval (g 0.39, 95% CI 0.06 to 0.73,  $I^2 = 80\%$ , eight studies, 785 participants, [Analysis 4.1](#)), but there was no beneficial effect of psychoeducation in the long-term interval (g 0.28, 95% CI -0.13 to 0.68,  $I^2 = 73\%$ , three studies, 462 participants, [Analysis 4.2](#)).

## **5 Subgroup analysis: Relaxation versus control condition**

One study (50 participants; [De Klerk 2004](#)) reported data comparing relaxation against a control condition on mental distress in the medium-term interval. Results reveal a large effect in favour of relaxation (g 1.15, 95% CI 0.67 to 1.63), whereas there was no beneficial effect of relaxation in the long-term interval (g 0.67, 95% CI -0.65 to 2.00,  $I^2 = 94\%$ , two studies, 124 participants, [Analysis 5.1](#)).

## **6 Subgroup analysis: Combined intervention versus control condition**

Studies comparing a combination of psychological interventions against a control condition revealed no beneficial effects on mental distress in the medium-term interval (g 0.05, 95% CI -0.16 to 0.26,  $I^2 = 0\%$ , three studies, 309 participants, [Analysis 6.1](#)), as well as there was no beneficial effect on mental distress in the long-

term interval (g 0.17, 95% CI -0.09 to 0.43,  $I^2 = 76\%$ , six studies, 725 participants, [Analysis 6.2](#)).

### Sensitivity analyses

We carried out sensitivity analyses to explore the effects of risk-of-bias components as well as to test the robustness of effects against 1) the exclusion of effect sizes being approximated due to missing statistical parameters in studies and 2) the exclusion of effect sizes which were not reliably estimated by means, standard deviations and sample sizes. We computed sensitivity analyses for each outcome separately. Only those sensitivity analyses with a significant change to overall findings are reported and shown in [Data and analyses](#).

### 7 Sensitivity analysis: Studies with adequate sequence generation

Studies with adequate sequence generation reported data on mental distress in the medium-term interval (g 0.44, 95% CI -0.12 to 1.00,  $I^2 = 88\%$ , four studies, 400 participants, [Analysis 7.1](#)) and in the long-term interval (g 0.15, 95% CI -0.20 to 0.51,  $I^2 = 79\%$ , four studies, 523 participants, [Analysis 7.2](#)). revealed a broader confidence interval compared to [Analysis 1.3](#) and [Analysis 1.4](#), indicating that the beneficial effect of psychological interventions on mental distress is not present in studies with adequate sequence generation.

### 8 Sensitivity analysis: Studies with adequate handling of incomplete outcome data

The beneficial effects of psychological intervention on mental distress in the medium-term ([Analysis 1.3](#)) and in the long-term interval ([Analysis 1.4](#)) did not persist in studies with adequate handling of incomplete outcome data (medium-term: g 0.15, 95% CI -0.07 to 0.36,  $I^2 = 54\%$ , six studies, 612 participants, [Analysis 8.1](#); long-term: g 0.10, 95% CI -0.18 to 0.37,  $I^2 = 73\%$ , four studies, 565 participants, [Analysis 8.2](#)).

### 9 Sensitivity analysis: Studies with study protocol available

Studies for which a study protocol was available revealed a broader confidence interval for data on mental distress in the medium-term interval (g 0.28, 95% CI -0.30 to 0.86,  $I^2 = 80\%$ , two studies, 213 participants, [Analysis 9.1](#)) as compared to [Analysis 1.3](#), indicating that the beneficial effect of psychological interventions on mental distress did not persist in studies with study protocol available.

## DISCUSSION

### Summary of main results

This systematic review investigated the efficacy of psychological interventions (psychoeducation, cognitive-behavioural methods, and relaxation) in adults undergoing open heart surgery.

19 studies (2164 participants) provided data on pain intensity, analgesic use, mental distress, mobility and time to extubation.

No study reported numbers of participants with at least a 50% pain reduction from baseline. Only one single study reported data on the number of people below a threshold of 30/100 mm VAS, indicating a null effect ([Parthum 2006](#)).

Psychological interventions for people undergoing open heart surgery were not beneficial for the prespecified primary outcome of pain intensity. Four studies reported data on pain intensity measured with continuous scales in the medium-term interval; five studies provided respective effect estimates for the long-term interval. The effect of psychological interventions on the reduction of postoperative pain intensity was not statistically significant in either time interval and did not meet the prespecified minimal clinical relevance cut-off. Since the number of studies reporting data on pain intensity was small and study quality was low, it might be likely that further research will change the confidence in this finding ([Summary of findings for the main comparison](#)).

For the secondary outcome of mental distress, the number of available studies was larger. This outcome was assessed in the medium-term interval in 12 studies and the long-term interval in 11 studies. A small positive treatment effect on mental distress initially supports a benefit of psychological interventions compared to control conditions both in the medium-term and the long-term interval. However, we have some concerns about the robustness of this initial finding. The heterogeneity between studies was very large and still remained high in sensitivity analyses with low risk of bias studies, and the effect did not persist in sensitivity analyses with low risk of bias studies. Further research is likely to improve the confidence in this finding; the quality of evidence for the outcome mental distress must currently be regarded as moderate in the medium-term interval and as low in the long-term interval ([Summary of findings for the main comparison](#)).

Subgroup analyses showed that psychoeducation is beneficial to achieving a reduction of mental distress in the medium-term interval. However, heterogeneity remains high in this analysis, limiting the interpretation of the finding.

Efficacy of psychological interventions for mental distress was no longer present in trials with an attention control group, both in the medium-term ([Anderson 1987](#); [Ku 2002](#); [Utriyaprasit 2010](#)) and the long term interval ([Pick 1994](#); [Utriyaprasit 2010](#); [Zarani 2010](#)). Subgrouping studies by type of control group or type of intervention did not reduce or help to identify sources of heterogeneity.

Other secondary outcomes were studied less often. Postoperative analgesic use was reported in only one trial ([Martorella 2012](#)). A small positive effect of borderline significance in favour of psychological interventions in the short-term interval was observed,



whereas there were no benefits of psychological intervention in the medium-term interval. Time to extubation was also assessed in only one trial (Deyirmenjian 2006) revealing a small positive effect of borderline significance in favour of psychological interventions in the short-term interval. However, these initial findings require replication from other research teams to improve confidence in these effects.

The evidence for the effect of psychological interventions on post-operative mobility was based on three studies in the medium-term interval and four studies in the long-term interval, showing that psychological interventions were not beneficial in improving post-operative mobility. Again, the quality of the evidence was low and further research is very likely to have an important impact on our confidence in the effect estimate.

## Overall completeness and applicability of evidence

This review summarises the efficacy of various types of psychological interventions and treatment formats. Included studies differed in the applied interventions and incorporated a variety of intervention time points and treatment providers. Additionally, the variety of hospital settings and healthcare systems of different countries increased the external validity of our results. On the other hand, the completeness and applicability of evidence were restricted due to the following reasons.

A majority of the primary and secondary outcomes (two-thirds of outcomes) were either not assessed in any of the studies, or were only assessed in a small number of studies. None of the primary studies reported the number of participants with pain intensity reduction of at least 50% from baseline (primary outcome), and only one study reported the number of participants below a threshold of 30/100 mm VAS. Although the experience of severe acute postoperative pain in the first 48 hours during ICU stay is one of the most disturbing problems in people undergoing open heart surgery, only two studies reported measures of pain intensity within this short-term interval (Parthum 2006; Martorella 2012). The evidence base for our main objectives was therefore very sparse. The rarity of this assessment might be explained by difficulties for participants in communicating during their ICU stay, since the presence of an endotracheal tube, residual effects of anaesthesia, sedative agents and changes in level of consciousness restrict communication to head nodding or upper limb movements (Gelinas 2007).

Neither the postoperative median time to remedication, nor the number of participants remedicated was reported in primary studies. We therefore could not draw any conclusions about the efficacy of psychological interventions on these parameters, known as an important key outcome of acute pain management (Moore 2011).

Only three studies used observer-reported outcome measures (Deyirmenjian 2006; Mahler 1998; Martorella 2012), while the

majority of studies used self-reported outcome measures only. Self-reported outcomes are frequently used in psychological intervention research, and are particularly important in evaluating the effects of psychological interventions on subjective outcomes like pain intensity and mental distress, since the patient's perspective is regarded as the most relevant. However, in trials with self-reported outcomes the outcome assessment is not blinded since the outcome assessors are the participants themselves, who are aware of the treatment content and might subsequently deduce their treatment allocation. It is plausible that participants' outcome assessments will be biased, because participants may have been given differing expectations of their recovery by study and medical personnel, which may have influenced their outcome assessments. Furthermore, it cannot be ruled out that participants have formed their own treatment expectations based on knowledge of their treatment allocation, which in turn has an impact on their judgement (Higgins 2011a). However, there is currently no clear evidence on whether non-blinded self-reports lead to an over- or underestimation of treatment effects for subjective outcomes in psychological intervention trials. We therefore assigned an unclear risk of detection bias to the corresponding trials. Moreover, it is not clear whether self-reported improvement in subjective outcomes is more sensitive to change than observer-reported measures. It has been demonstrated that self-reported measures and observer-rated measures do not necessarily give equivalent assessments of intervention effects for depression (Cuijpers 2010). Future trials should consider credible placebo-control groups to minimise the risk that social desirability bias influences participant outcomes (Quality of the evidence).

Some of the measures (e.g. Beck Anxiety Inventory, Beck 1988; Beck Depression Inventory, Beck 1996) are designed for clinical samples and are prone to produce floor effects in non-clinical samples, even with baseline measures of depression and anxiety being elevated in the context of cardiac surgery. Some studies used rating scales for mental distress, mobility, or pain that are not routinely applied in clinical practice or research (e.g. Postoperative Affect Scale (Sime 1976), and Well-being Scale (Zerksen 1970)). The reliability and validity of these measures might be limited, leading to unreliable data. We therefore recommend the use in future trials of psychometrically sound instruments which are common in routine practice and research.

Five studies used skills teaching (e.g. relaxation procedure) or a taped intervention which participants had to apply by themselves (De Klerk 2004; Moore 2001; Pick 1994; Sørli 2007; Utriya 2010). Only Moore 2001 and Utriya 2010 measured adherence to the intervention and found acceptable adherence rates. The other three studies did not provide data on adherence. Although listening to a tape was only one part of the interventions, it is possible that non-adherence of participants might have reduced the effects of these interventions. Measuring adherence should therefore be considered in future trials, to rule out non-adherence effects on intervention efficacy.



Our review comprises substantial clinical heterogeneity across studies on the intervention (contents, provider, dose, and duration) and outcome measures (e.g., various ways to assess mental distress or mobility). Consequently, tests of statistical heterogeneity indicated a large amount of heterogeneity in the analyses. However, subgroup analyses and sensitivity analyses could not explain the sources of heterogeneity. It is reasonable to assume that other moderators (e.g., dose and duration of intervention) might be present which have not been prespecified for data extraction. Subgroup analyses of the type of intervention for outcomes other than mental distress were not feasible, due to the small number of trials for each outcome, so that we do not know how different intervention methods might work for these outcomes. However, future updates of this review may include more studies enabling us to conduct these analyses. The applicability of results is currently limited, due to a relatively small number of eligible randomised controlled trials (RCTs) with small sample sizes.

## Quality of the evidence

In total, we screened 6179 records to retrieve 19 eligible RCTs with data from 2164 people undergoing open heart surgery. The majority of studies provided insufficient information to derive a risk of bias judgement (Figure 2; Figure 3). More than 50% of the studies did not adequately report information on methods of allocation concealment or blinding, and are rated as being at unclear risk of bias.

Performance bias results from systematic differences between groups in the care that is provided (Higgins 2011a). In pharmacological treatment studies controlling for performance bias is typically achieved through the blinding of participants and study personnel to the treatment condition. In psychological intervention trials it is improbable that treatment delivery can be double-blind, as therapists will know what they are delivering and participants will also be aware of treatment content. Non-blinding of participants could bias the results by affecting the outcomes (Overall completeness and applicability of evidence). This may for example be due to a lack of expectations for treatment success in a control group (Higgins 2011a). In psychological intervention trials the prevention of performance bias can partly be addressed by strategies to compensate for the lack of blinding, e.g. by ensuring equivalence of treatment credibility and structural equivalence if different interventions are compared (Baskin 2003). Another strategy to account for the risk of performance bias is the assessment of expectations of treatment benefits and to ask the participants to guess their allocation (Baskin 2003).

For all but two studies (Guo 2012; Martorella 2012, 205 participants) the study protocol was not available, indicating an unclear risk of selective reporting bias for 89% of the studies.

The overall quality of the body of evidence was rated as low (Summary of findings for the main comparison). Reasons for downgrading the RCTs were as follows:

Number of participants with pain intensity below a threshold of 30/100 mm VAS: this result was based on a rather small study (73 participants; Parthum 2006) with a high risk for selection bias and detection bias. This is regarded as very low quality evidence, and we are uncertain about this effect estimate.

Continuous measures of pain intensity in the medium-term interval were provided in four RCTs (Guo 2012; Martorella 2012; Shelley 2007; Utriyaprasit 2010; 413 participants). There was no indicator for inconsistency ( $\text{Tau}^2 = 0.02$ ;  $\text{Chi}^2 = 4.55$ ,  $\text{df} = 3$  ( $P = 0.21$ );  $I^2 = 34\%$ ). Sensitivity analyses restricted to low risk of bias studies did not yield divergent results. However, only two out of four studies (Guo 2012, 153 participants; Martorella 2012, 60 participants) were rated as high quality trials. In addition, a small body of evidence (four trials with 413 participants) did not allow robust conclusions; hence, the quality of evidence was rated as moderate. Pain intensity measured with continuous scales in the long-term interval was reported in three studies (Heidarnia 2005; Shelley 2007; Utriyaprasit 2010, 280 participants). Although results were consistent ( $\text{Tau}^2 = 0.0$ ;  $\text{Chi}^2 = 1.10$ ,  $\text{df} = 2$  ( $P = 0.58$ );  $I^2 = 0\%$ ) and sensitivity analyses restricted to low risk of bias studies did not yield divergent results, the quality of evidence was rated as low. Reasons were that there was a small body of evidence, and that one of three trials (Heidarnia 2005) suffered from high risk of selection bias and attrition bias.

Evidence for analgesic was present in only one trial (Martorella 2012), which was rated as a high quality study, but with a small sample size (60 participants). Since the precision of the effect estimate was low and only one study provided evidence at all, we rated the quality of evidence for short-term and medium-term analgesic use as moderate.

Twelve trials (Anderson 1987; Bergmann 2001; De Klerk 2004; Deyirmenjian 2006; Guo 2012; Ku 2002; Mahler 1999; Martorella 2012; Parent 2000; Shelley 2007; Sørle 2007; Utriyaprasit 2010; 1144 participants) provided data for effect estimation on the reduction of mental distress in the medium-term interval. However, high levels of heterogeneity occurred ( $\text{Tau}^2 = 0.16$ ;  $\text{Chi}^2 = 53.81$ ,  $\text{df} = 11$  ( $P < 0.00001$ );  $I^2 = 80\%$ ) and the effect was no longer present in sensitivity analyses restricted to studies with adequate sequence generation, adequate handling of incomplete outcome data, and low risk of selective reporting bias. Hence, the quality of evidence was rated as low. Long-term effects on mental distress were reported in eleven trials (De Klerk 2004; Gilliss 1993; Heidarnia 2005; Mahler 1999; Moore 2001; Parent 2000; Pick 1994; Shelley 2007; Sørle 2007; Utriyaprasit 2010; Zarani 2010; 1320 participants). Again, high levels of heterogeneity appeared ( $\text{Tau}^2 = 0.12$ ;  $\text{Chi}^2 = 50.69$ ,  $\text{df} = 10$  ( $P < 0.00001$ );  $I^2 = 80\%$ ) and the effect did not persist in sensitivity analyses restricted to studies with adequate sequence generation, adequate handling of incomplete outcome data, and low risk of selective reporting bias. Accordingly, we judged the quality of evidence as low.

Study results from three trials (Mahler 1998; Parent 2000;

Utriyaiprasit 2010; 444 participants) investigating effects on postoperative mobility in the medium-term interval yielded high levels of heterogeneity ( $\text{Tau}^2 = 0.12$ ;  $\text{Chi}^2 = 9.84$ ,  $\text{df} = 2$  ( $P = 0.01$ );  $I^2 = 80\%$ ). We did not regard three studies as a sufficient body of evidence to draw robust conclusions and judged the quality of evidence as low. The same was true for long-term effects on postoperative mobility which were reported in four studies (Gilliss 1993; Heidarnia 2005; Parent 2000; Utriyaiprasit 2010; 423 participants) with high levels of heterogeneity ( $\text{Tau}^2 = 0.15$ ;  $\text{Chi}^2 = 16.92$ ,  $\text{df} = 3$  ( $P = 0.00073$ );  $I^2 = 78\%$ ). Again, we judged the quality of evidence as low.

Time to extubation was reported by only one study (Deyirmenjian 2006, 110 participants) with a high risk of selection bias, but low risk of detection bias due to blinded outcome assessors. However, the precision of the effect estimate was low ( $-0.00$  to  $0.75$ ) and data from one study do not allow robust conclusions. The quality of evidence was rated as very low.

Overall, the quality of the body of evidence on the efficacy of psychological interventions for acute pain after open heart surgery cannot be regarded as sufficient to draw robust conclusions.

### Potential biases in the review process

Since we adhered strictly to the Cochrane Collaboration guidelines (Higgins 2011c, Chandler 2013, PaPaS 2011), potential biases should have been reduced. However, some bias might have been introduced.

We attempted to minimise publication bias by performing a comprehensive literature search and including studies without language restrictions. We contacted each author of an included study in order to identify unpublished study material. We received an answer from seven primary study authors who were not aware of any unpublished trial or ongoing studies. Furthermore, we searched the ProQuest Dissertation and Thesis Database to identify any unpublished studies. However, we were not able to retrieve any unpublished studies, and all 19 included studies were published papers. We did not find evidence of a publication bias with regard to the secondary outcome mental distress measured in the medium-term and the long-term interval.

To avoid potential bias in the process of selecting studies, two review authors independently screened titles and abstracts of retrieved articles, with recourse to a third review author in cases of disagreement. Data extraction was also independently performed in duplicate by two review authors, and a consensus data set for each study was used for meta-analyses. We resolved disagreement by consultation with a third review author.

Missing statistical parameters in primary studies are a well-known source of bias. In one study missing information could be retrieved by personal contact with the author who supplied information that was not extractable from the manuscript (Shelley 2007). In another trial, non-significant results were mentioned without reporting any related statistical parameters (Pick 1994); hence, we

used a conservative approach and set effect estimates to zero. Other studies failed to provide standard deviations for each group (Gilliss 1993; Heidarnia 2005; Zarani 2010). Hence, we had to calculate standard deviations from standard errors, or to estimate them from studies using the same scale and measurement time point. However, a sensitivity analysis of the robustness of meta-analysis results showed no change after exclusion of the studies with missing information (Shelley 2007; Pick 1994; Gilliss 1993; Heidarnia 2005; Zarani 2010).

### Agreements and disagreements with other studies or reviews

There are no previous systematic reviews investigating the effects of psychological interventions during hospital stay in people undergoing open heart surgery. We therefore compared our findings to reviews summarising evidence on psychological interventions in people with coronary heart disease or undergoing similar painful medical procedures.

Johnston 1993 investigated the effectiveness of preoperative psychological interventions in adults undergoing elective surgical procedures under general anaesthesia. They included 38 randomised controlled trials comparing psychological interventions to treatment-as-usual or attention control group. Johnston 1993 included one trial that we also include in our review (Anderson 1987), and two trials that were excluded from our review because of small sample size (Postlethwaite 1986) and non-random allocation procedure (Surman 1974). Results of Johnston 1993 are in line with the findings of our review with respect to mental distress, but not with respect to pain and pain medication. For the latter outcomes, the Johnston 1993 review found moderate to large effects in favour of psychological interventions.

One intervention trial included in the present review (De Klerk 2004) is also included in the review of Schnur 2008, which investigated the effects of hypnotherapeutic interventions in children and adults undergoing medical procedures. Schnur 2008 summarized data of 26 randomized-controlled trials comparing hypnotherapeutic interventions against treatment-as-usual or attention control group. They also included another two trials with cardiac surgical patients that were excluded from the present review for reasons of small sample size (Ashton 1997) and inclusion of non-elective patients (Blankfield 1995). The results of Schnur 2008 are comparable to the present review; hypnosis was found to be effective to reduce emotional distress associated with medical procedures.

In a Cochrane review of 24 trials, Whalley 2011 systematically reviewed the effects of psychological interventions within cardiac rehabilitation for people with coronary heart disease. In line with the findings in our review, Whalley 2011 concluded that psychological interventions resulted in small improvements in depression and anxiety.

## AUTHORS' CONCLUSIONS

### Implications for practice

Evidence revealed that psychological interventions were not effective in reducing pain intensity after open heart surgery. This conclusion is based on pain data measured with continuous scales, as there were insufficient data for more informative pain outcomes. No study reported data on the primary outcome (number of participants with pain reduction of at least 50% from baseline) and only one study reported data on the number of participants below 30/100 mm in the VAS in pain intensity (Parthum 2006). Altogether, the current evidence does not clearly support the use of psychological interventions to reduce pain in open heart surgery patients.

Evidence also showed that psychological interventions did not enhance mobility after open heart surgery. There is low quality evidence that psychological interventions have favourable effects on mental distress, but these results might be prone to bias in primary studies. More precisely, best evidence from two large trials at low risk of bias showed inconsistent effects on mental distress: Guo 2012 found positive treatment effects, while Martorella 2012 reported no beneficial effect on mental distress.

### Implications for research

For the majority of outcomes (two-thirds) we could not perform a meta-analysis because either the outcomes were not measured, or data were only provided by one trial. Since our review is limited by a lack of data for primary and secondary outcomes (particularly dichotomous pain outcome data), future trials which report dichotomous pain outcomes are urgently needed.

The quality of evidence for benefits of psychological interventions on mental distress is low. However, the meta-analysis results suggested that psychological interventions might have the potential to enable participants to cope successfully with stressors of open heart surgery. Successful coping prevents the development of an adjustment disorder or a reactive type of depression, which in turn have been hypothesised to be associated with the aetiology of postoperative depression (Peterson 2002). Several studies have demonstrated an association between postoperative depression and mortality or cardiac events after cardiac surgery, although the behavioural and biological mechanisms are as yet poorly understood (see for a review Tully 2012). Further studies are required to evaluate the effects of in-hospital psychological interventions in people undergoing cardiac surgery on the development of postoperative depression and subsequently-occurring cardiac events.

It remains unclear whether the effects observed in trials with a standard care control group are non-specific or are caused by specific components of the active intervention, since the effect on mental distress is no longer present in trials with an attention control group (Anderson 1987; Utriya 2010; Pick 1994; Zarani

2010). Future high-quality trials should test the extent to which psychological interventions contribute any specific effects above and beyond the non-specific effects of the additional attention and caring support received during hospitalisation.

In our meta-analysis, we did not evaluate any harm associated with psychological interventions since none of the primary studies reported adverse intervention effects. Adverse events might be of interest to the population of people undergoing open heart surgery, and should be collected in forthcoming trials, as studies in people after a critical life event have shown some negative effects of psychological interventions.

The large heterogeneity in effects on mental distress needs to be explained in future research. Subgroup analyses with respect to treatment variables such as treatment provider, treatment content, dose and time point of treatment, might contribute to identifying sources of heterogeneity.

The majority of studies did not provide information about skills or competence of the treatment provider (e.g., formal qualification or training). Training and qualifications, as well as checking the sessions, are important aspects of quality assurance, as psychological interventions rely very much on the skills of the practitioner. Future trials should describe the qualifications and training of the staff, and should include session checks on competence.

It might be reasonable to assume the presence of participant variables which moderate the effects of psychological interventions. For example, it has been shown for people with cancer that those with higher levels of mental distress may benefit more from psychological interventions than those with normal levels of mental distress, or those with only a marginally increased level (Coyne 2006; Hart 2012). There are further findings indicating that control appraisals do moderate the effect of psychoeducational interventions on distress and pain (Shelley 2007). There might be subgroups of participants who are unaffected or who even experience more distress after the intervention than they would have experienced without it. Future studies should report results for subgroups of participants in order to examine differential effects.

Future research should also focus on the underlying mechanisms of psychological interventions in the context of cardiac surgery, as these mechanisms are not yet understood. One possible underlying mechanism might be patients' compliance to medical treatment recommendations. It might be reasonable to expect that people undergoing open heart surgery with reduced mental distress after surgery are more compliant with medical treatments, recommendations for lifestyle change and participation in cardiac rehabilitation, as has already been shown for people recovering from acute coronary events (Rieckmann 2006; Ziegelstein 2000; Glazer 2002). Understanding how psychological interventions work is crucial to designing psychological interventions that target active change mechanisms.

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**Zigmond 1983**

Zigmond AS, Snaith RP. The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavica* 1983;**67**(6):361–70. [PUBMED: 6880820]

**Zung 1965**

Zung WW. A self-rating depression scale. *Archives of General Psychiatry*. 1965/01/01 1965; Vol. 12:63–70. [PUBMED: 14221692]

**Zung 1974**

Zung WW. The measurement of affect: depression and anxiety. In: Pichot P, Oliver-Martin R editor(s). *Psychological Measurement in Psychopharmacology*. Basle: Karger, 1974.

**References to other published versions of this review****Tefikow 2012**

Tefikow S, Barth J, Trelle S, Strauss BM, Rosendahl J. Psychological interventions for acute pain after open heart surgery. *Cochrane Database of Systematic Reviews* 2012, Issue 7. [DOI: 10.1002/14651858.CD009984]

\* Indicates the major publication for the study

## CHARACTERISTICS OF STUDIES

### Characteristics of included studies [ordered by study ID]

#### Anderson 1987

Methods	<p>Randomised controlled trial</p> <p>Study duration: not reported</p> <p>Date study was conducted: not reported</p>
Participants	<p><i>Setting</i></p> <p>Thoracic-Cardiovascular Surgery Clinic, University Iowa, USA</p> <p><i>Inclusion criteria</i></p> <p>Male gender</p> <p>Coronary artery bypass surgery</p> <p>Suffering only from coronary artery disease and without surgery within 5 years</p> <p><i>Exclusion criteria</i></p> <p>Previous surgery within 5 years</p> <p>Emergency surgery</p> <p><i>Baseline data</i></p> <p>N = 60 (intervention A = 20, intervention B = 20, control = 20)</p> <p>Left ventricular ejection fraction: intervention A 60%, intervention B 62%, control 60%</p> <p>Mean number of grafts: 4</p> <p>Mean age: 59.1 years</p> <p>Education: 47% not completed high school, 38% high school, 15% college undergraduate or beyond</p>
Interventions	<p><i>Routine care for all participants</i></p> <p>Routine hospital preparation, visit by a nurse discussing 2 pamphlets (outlining the surgical and hospital procedures)</p> <p><i>Attention control group</i></p> <p>30-min interview with investigator focusing on neutral, hospital-related topics</p> <p><i>Intervention groups</i></p> <p>Group A) Psychoeducation</p> <p>Detailed information about the procedures and sensations participants would experience</p> <p>18-min videotape <i>Living Proof</i> (Keach 1981) presenting interviews with recovered cardiac surgery patients and following a CABG patient from admission to discharge</p> <p>6-min audio tape outlining specific procedures in the University Hospital of Iowa and providing information about typical sensations during hospitalisation</p> <p>Group B) Psychoeducation</p> <p>Provision of the same information as in Intervention group A (videotape, audiotape) + 42-slide show explaining the postoperative exercise regimen</p> <p>Participants practised exercises until they could perform them correctly</p>

Outcomes	<i>Self-reported postoperative mental distress</i> Negative emotions Postoperative Affect Scale ( <a href="#">Sime 1976</a> ) Continuous measure (9 items, 5-point scale, lower scores indicate less negative affect) Participant-reported 2nd interval (7th postop. day)  <i>Self-reported postoperative mental distress</i> State-Trait Anxiety Inventory (STAI, <a href="#">Spielberger 1970</a> ), state anxiety score Continuous measure (score ranges from 20 - 80, higher scores indicate higher anxiety) Participant-reported 2nd interval (7th postop. day) No adverse events reported.	
Notes	Sources of funding: National Institutes of Health (NIH) Grant HL07385 and by Grant RR59 from the General Clinical Research Centers Program, Division of Research Resources, NIH Conflicts of interests: not reported	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Low risk	“The use of CRC facilities assured that cardiovascular unit nurses and physicians remained blind to patients’ treatment assignments.” (p.515)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Unclear risk	No information given about numbers of participants who were assessed postoperatively or number of drop-outs
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Bergmann 2001**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<i>Setting</i> University Clinic Graz, Austria <i>Inclusion criteria</i> Elective open heart surgery patients <i>Exclusion criteria</i> Acute or recent myocardial infarction (within the last 6 weeks) Percutaneous transluminal coronary angioplasty Angina unresponsive to medical therapy and patient therefore scheduled for urgent operation, Intake of psychopharmaceuticals or thyroid hormones before surgery, Patients waiting for more than 3 days for their operation  <i>Baseline data</i> N = 60 (intervention 30, control 30) Coronary artery bypass surgery 65%, heart valve operation 35% (Ejection fraction: intervention 58%/control 56%) Male gender: intervention 60%; control 53% Mean age: intervention 62 years; control 59 years NYHA II+IV 86.7%
Interventions	<i>Routine care for all participants</i> Routine medical information through informative pamphlet with 2 illustrations covering 4 points (pre-operative course and preparation for the operation, surgical technique, postoperative course, possibility of intra- and postoperative complications)  <i>Control group</i> Routine care (TAU) <i>Intervention group</i> Psychoeducation Extensive oral information given preoperatively by surgeon (same information as in pamphlet), opportunity to talk about peri-operative concerns or personal problems (twice a day, at least 20 mins) Surgeon had no training in psychotherapy but was supervised by a graduate psychotherapist before the study
Outcomes	<i>Postoperative mental distress</i> Anxiety State-Trait Anxiety Inventory (STAI, <a href="#">Spielberger 1970</a> ), state anxiety score Continuous measure (score ranges from 20 - 80, higher scores indicate higher anxiety) Participant-reported 2nd interval (6th postop. day)  <i>Postoperative mental distress</i> Well-being Well-being Scale ( <a href="#">Zerssen 1970</a> )

**Bergmann 2001** (Continued)

	Continuous measure (lower scores indicate positive condition) Participant-reported 2nd interval (6th postop. day) No adverse events reported.	
Notes	Sources of funding: not reported Conflicts of interests: not reported	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	Only 1 of 30 participants in intervention group did not complete, reasons stated, no differences in baseline measures from rest of the group
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**De Klerk 2004**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<i>Setting</i> Unitas hospital, Pretoria, Gauteng Province, South Africa <i>Inclusion criteria</i> Patients undergoing coronary artery bypass surgery <i>Exclusion criteria</i> Not described

	<p><i>Baseline data</i></p> <p>N = 50 (intervention 25, control 25)</p> <p>Male gender: 100%</p> <p>Mean age: 56 years</p> <p>Education: 12 years</p>
Interventions	<p><i>Routine care for all participants</i></p> <p>Not described</p> <p><i>Control group</i></p> <p>Routine care (TAU)</p> <p><i>Intervention group</i></p> <p>Relaxation</p> <p>Hypnotherapeutic ego strengthening, including a progressive relaxation induction and a special-place deepening technique; a metaphor focusing on spiritual inner strength and age progression was introduced; 2nd session included a preoperative rehearsal</p> <p>Preoperatively, 2 x 60-minute sessions individually in a private room the evening preceding surgery and the morning thereof</p> <p>Repetition of inner strength and age progression intervention on audiocassette</p> <p>3 postoperative sessions, 1 session daily, voice of principal investigator, used with classical music</p>
Outcomes	<p><i>Postoperative mental distress</i></p> <p>Depression</p> <p>Beck Depression Inventory (BDI-II, <a href="#">Beck 1996</a>)</p> <p>Continuous measure (sum of 21 items, scores ranging from 0 - 63; higher scores indicate progressively severe levels of depression)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (6 weeks postoperatively)</p> <p><i>Postoperative mental distress</i></p> <p>Depression</p> <p>Profile of Mood States (POMS, <a href="#">McNair 1992</a>) - sub scale depression</p> <p>Continuous measure (higher scores indicate greater depression)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (6 weeks postoperatively)</p> <p><i>Postoperative mental distress</i></p> <p>Anxiety</p> <p>Profile of Mood States (POMS, <a href="#">McNair 1992</a>) - sub scale anxiety</p> <p>Continuous measure (higher scores indicate greater anxiety)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (6 weeks postoperatively)</p> <p>No adverse events reported.</p>



**De Klerk 2004** (Continued)

Notes	Sources of funding: not reported Conflicts of interests: not reported	
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Low risk	“Nursing personnel caring for the two groups in the ICU and relevant open wards received no education or insight, so as not to influence participants’ responses” (p. 83)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Deyirmenjian 2006**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<p><i>Setting</i> Cardiac surgery unit, University hospital in Beirut, Lebanon</p> <p><i>Inclusion criteria</i> Less than 80 years old First time, coronary artery bypass surgery</p> <p><i>Exclusion criteria</i> History of psychiatric disorder Spouse operated for coronary artery bypass surgery</p>

	<i>Baseline data</i> N = 110 (intervention 57, control 53) Male gender: intervention 83%; control 84% Mean age: intervention 62.4 years; control 58.6 years Married: intervention 83%; control 86% Education: intervention 16.4 years; control 16.3 years Employed: intervention 53%; control 60%	
Interventions	<i>Routine care for all participants</i> Routine hospital protocol almost without preoperative education  <i>Control group</i> Routine care (TAU) <i>Intervention group</i> Psychoeducation Preoperative educational session including conversations about what to expect in the Cardiac Surgery Unit in terms of equipment used, visiting hours for the family members; followed by an explanation and demonstration of respiratory exercises, leg exercises, and possible complications; discussion of pain management and early ambulation; possibility of answering questions; tour to the cardiac surgery unit	
Outcomes	<i>Postoperative mental distress</i> Anxiety Beck Anxiety Inventory (BAI, <a href="#">Beck 1988</a> ), Arabic version Continuous measure (sum of 21 items, total score ranges from 0 - 63, higher scores indicate greater anxiety) Participant-reported 2nd interval (2 days before discharge)  <i>Time to extubation</i> Hours to extubation after awakening from anaesthesia Continuous measure (higher scores indicate negative effect) Observer-reported 1st interval (after awakening from anaesthesia) No adverse events reported.	
Notes	Sources of funding: The National Council for Research and Development in Lebanon Conflicts of interests: not reported	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	“They were randomly assigned to the groups of comparison: patients with odd admission number were assigned to the experimental group, while patients with pair admission number were assigned to the control group.” (p. 113)

Allocation concealment (selection bias)	High risk	Allocation based on admission numbers
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Observer-reported outcomes	Low risk	Time to extubation: "Nurses collected data related to measurements of [...] time to extubation. The nurses were not aware whether the patient belonged to the experimental or control group" (p.114)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Self-reported outcomes
Incomplete outcome data (attrition bias) short-term	Low risk	No missing data
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

## Gilliss 1993

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<p><i>Setting</i> 2 hospitals in the western United States (large community hospital with an active cardiovascular surgery practice, health sciences research centre)</p> <p><i>Inclusion criteria</i> Age between 25 and 75 years Coronary artery bypass surgery (CABG), CABG and valve replacement or repair, valve replacement or repair, double valve replacement or repair, septal repair, or repeats of any of these procedures Conversant in English Available for telephone follow-up for 6 months after surgery With a primary caregiver also available for 6 months follow-up and consenting to participate</p> <p><i>Exclusion criteria</i> Aneurysms, aortic arch repairs, chronic ventricular arrhythmia, automatic implantable cardioverter defibrillator, or idiopathic hypertrophic subaortic stenosis</p> <p><i>Baseline data</i></p>

	<p>N = 156 (intervention 75, control 81)</p> <p>Coronary artery bypass surgery: intervention 61%; control 63%, Valve surgery: intervention 31%; control 26%, CABG + valve: intervention 5%; control 7%, other: intervention 3%; control 4%</p> <p>Male gender: intervention 81%; control 79%</p> <p>Mean age: intervention 59 years; control 60 years</p> <p>NYHA III+IV: intervention 41%; control 49%</p>
Interventions	<p><i>Routine care for all participants</i></p> <p>In-hospital screening by individual participants of slide-tape programmes from the American Heart Association series, <i>An Active Partnership</i>, and a post hospital visit at 6 weeks to the cardiac surgeon</p> <p><i>Control group</i></p> <p>Routine care (TAU)</p> <p><i>Intervention group</i></p> <p>Psychoeducation, Cognitive-behavioural intervention</p> <p>Intervention I: Postoperative in-hospital education (typically 2 days after discharge from the ICU) for participants and partners on emotional reactions to surgery; slide-tape presentation <i>Working Together for Recovery</i> addressing: understanding anxiety, anticipating depression, solving new problems, identifying areas of potential conflict with family members, common feelings and reactions of participants and partners were identified, basic information on conflict resolution offered; education was followed by a private session with a study nurse for individualisation of the content</p> <p>Intervention II: telephone contact on a weekly basis through the 1st 4 weeks after discharge and again at 6 and 8 weeks; provision of frequent and individualised support, reinforcement of the educational content of intervention I, provision of information for formation of self-efficacy expectations</p>
Outcomes	<p><i>Postoperative mental distress</i></p> <p>Psychological distress/ Psychological functioning</p> <p>Profile of Mood States (POMS, <a href="#">McNair 1971</a>) - total score</p> <p>Continuous measure (sum of 65 items measured on 5-point scale; higher scores indicate greater distress)</p> <p>Participant-reported</p> <p>3rd interval (4 weeks after surgery, 12 weeks after surgery, 24 weeks after surgery)</p> <p><i>Postoperative levels of mobility</i></p> <p>Walking</p> <p>Activity checklist (<a href="#">Jenkins 1985</a>), walking items</p> <p>Continuous measure (yes/no; number of completed activities in the previous 24-hour period; higher scores indicate greater ambulation)</p> <p>Participant-reported</p> <p>3rd interval (4 weeks after surgery, 8 weeks after surgery, 12 weeks after surgery, 24 weeks after surgery)</p> <p><i>Postoperative levels of mobility</i></p> <p>Lifting</p> <p>Activity checklist (<a href="#">Jenkins 1985</a>), lifting items</p>

	<p>Continuous measure (yes/no; number of completed activities in the previous 24-hour period; higher scores indicate greater ambulation)</p> <p>Patient-reported</p> <p>3rd interval (4 weeks after surgery, 8 weeks after surgery, 12 weeks after surgery, 24 weeks after surgery)</p> <p><i>Postoperative levels of mobility</i></p> <p>Climbing</p> <p>Activity checklist (Jenkins 1985), climbing items</p> <p>Continuous measure (yes/no; number of completed activities in the previous 24-hour period; higher scores indicate greater ambulation)</p> <p>Participant-reported</p> <p>3rd interval (4 weeks after surgery, 8 weeks after surgery, 12 weeks after surgery, 24 weeks after surgery)</p> <p><i>Postoperative levels of mobility</i></p> <p>General activity</p> <p>Activity checklist (Jenkins 1985), general activity items</p> <p>Continuous measure (yes/no; number of completed activities in the previous 24-hour period; higher scores indicate greater ambulation)</p> <p>Participant-reported</p> <p>3rd interval (4 weeks after surgery, 8 weeks after surgery, 12 weeks after surgery, 24 weeks after surgery)</p> <p>No adverse events reported.</p>	
Notes	<p>Sources of funding: grant from the National Center for Nursing Research, National Institutes of Health, U.S. Department of Health and Human Services (2RO1-NR-01031)</p> <p>Conflicts of interests: not reported</p>	
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	“A cluster-randomized control design was used [...] Clusters, stratified by hospital, were randomized to be either experimental or control by use of a computer program for generating random numbers.” (p. 127)
Allocation concealment (selection bias)	Low risk	“The random assignment of the cluster was not disclosed until a patient in the cluster had reached the point where the experimental intervention differed from the control.” (p. 127)
Blinding of medical personnel (performance bias)	Unclear risk	Not described

Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	“intent to treat” analyses were conducted (p. 129)
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Guo 2012**

Methods	Randomised controlled trial Study duration: 15 months Date study was conducted: 1st December 2009 - 17th March 2010
Participants	<p><i>Setting</i> Cardiac surgical wards of two public hospitals in Luoyang, China</p> <p><i>Inclusion criteria</i> 18 years or older First-time elective cardiac surgery (coronary artery bypass grafting, valve surgery, congenital and other open heart surgery) Able to speak, read, and write Chinese</p> <p><i>Exclusion criteria</i> Emergency cases Patients who had undergone cardiac surgery on a previous occasion</p> <p><i>Baseline data</i> N = 153 (intervention 76, control 77) Coronary artery bypass surgery: intervention 49%; control 43%, valve surgery: intervention 32%; control 36%, congenital surgery or others: intervention 20%; control 21% Male gender: intervention 58%; control 52% Mean age: intervention 52 years; control 52.3 years Married: intervention 78%; control 86% Education &gt;9 years: intervention 26%; control 27% Employment: intervention 21%; control 25%</p>
Interventions	<p><i>Routine care for all participants</i> Unstructured verbal information about surgery and anaesthesia, 2 separate visits from surgeon and anaesthetist, responsive information from cardiac nurses on the ward, 1 day before surgery</p> <p><i>Control group</i> Routine care (TAU)</p>

	<p><i>Intervention group</i></p> <p>Psychoeducation</p> <p>Distribution of information leaflet <i>Your Heart Surgery</i> (simple texts and diagrams); provision of 15 - 20 min verbal advice by specialist cardiac nurse; specifically tailored procedural and instructional information throughout cardiac surgery patients' journey from admission to hospital discharge</p> <p>2 - 3 days before surgery</p>
Outcomes	<p><i>Postoperative mental distress</i></p> <p>Anxiety</p> <p>Hospital Anxiety and Depression Scale (HADS, Chinese-Cantonese version, <a href="#">Leung 1999</a>), anxiety sub scale</p> <p>Continuous measure (sum of 7 items measured on 4-point scale, scores range from 0 to 21; higher scores indicate greater anxiety)</p> <p>Participant-reported</p> <p>2nd interval (7 days after surgery)</p> <p><i>Postoperative mental distress</i></p> <p>Depression</p> <p>Hospital Anxiety and Depression Scale (HADS, Chinese-Cantonese version, <a href="#">Leung 1999</a>), depression sub scale</p> <p>Continuous measure (sum of 7 items measured on 4-point scale, scores range from 0 to 21; higher scores indicate greater depression)</p> <p>Participant-reported</p> <p>2nd interval (7 days after surgery)</p> <p><i>Postoperative pain intensity</i></p> <p>Average pain</p> <p>Brief Pain Inventory-short form, pain severity item for average pain (BPI-C, Chinese version; <a href="#">Wang 1996</a>)</p> <p>Continuous measure (10cm visual analogue scale; higher scores indicate greater pain)</p> <p>Patient-reported</p> <p>2nd interval (7 days after surgery)</p> <p><i>Postoperative pain intensity</i></p> <p>Current pain</p> <p>Brief Pain Inventory-short form, pain severity item for current pain (BPI-C, Chinese version; <a href="#">Wang 1996</a>)</p> <p>Continuous measure (10 cm visual analogue scale; higher scores indicate greater pain)</p> <p>Participant-reported</p> <p>2nd interval (7 days after surgery)</p> <p>No adverse events reported.</p>
Notes	<p>Sources of funding: PhD studentship by the School of Nursing, Midwifery and Physiotherapy, the University of Nottingham</p> <p>No conflict of interest declared by the authors</p>
<i>Risk of bias</i>	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"The randomization list was prepared by AA using the 'ralloc' command in Stata version 9.2" (p.131)
Allocation concealment (selection bias)	Low risk	"Randomization was implemented by PG using a series of consecutively numbered, opaque, sealed envelopes. The envelope was opened in the presence of the participant after baseline assessment was completed." (p.131)
Blinding of medical personnel (performance bias)	Low risk	"Participants in the preoperative education group were asked not to inform clinical staff about their allocation during the trial." (p. 131)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	Missing outcome data balanced in numbers and similar reasons for missing data across groups
Selective reporting (reporting bias)	Low risk	Study protocol is available ( <a href="http://www.controlled-trials.com/ISRCTN87451169">www.controlled-trials.com/ISRCTN87451169</a> )

**Heidarnia 2005**

Methods	Randomised controlled trial Study duration: 5 months Date study was conducted: April 2002 - August 2002
Participants	<p><i>Setting</i> Shahid Rajaei Heart Hospital in Teheran, Iran</p> <p><i>Inclusion criteria</i> Aged 40 to 65 years Elective coronary artery bypass surgery Atherosclerosis diagnosis by angiography</p> <p><i>Exclusion criteria</i> Not described</p> <p><i>Baseline data</i> N = 70 (intervention 35, control 35) Male gender: 100%</p>



	Mean age: intervention 53.5 years; control 52.8 years
Interventions	<p><i>Routine care for all participants</i> Not described</p> <p><i>Control group</i> Routine care (TAU)</p> <p><i>Intervention group</i> Psychoeducation, Cognitive-behavioral intervention Preoperative health educational planning according to Mico's Model, face-to-face and booklet with focus on exercise, diet, healthy sexual function, deep breathing, anatomy and physiology of the heart, surgery procedure, "planning phase": 3 group meetings each 20 - 25 min., "implementation phase": 3 educational meetings each 10 - 20 mins</p>
Outcomes	<p><i>Postoperative pain intensity</i> Pain Nottingham Health Profile (NHP), pain score Continuous measure (score from 0 - 100; higher scores indicating higher levels of pain) Participant-reported 3rd interval (4 weeks after surgery)</p> <p><i>Postoperative mental distress</i> Emotional reactions/distress Nottingham Health Profile (NHP), emotional reactions score Continuous measure (score from 0 - 100; higher scores indicating higher levels of distress) Participant-reported 3rd interval (4 weeks after surgery)</p> <p><i>Postoperative levels of mobility</i> Physical mobility Nottingham Health Profile (NHP), physical mobility score Continuous measure (score from 0 - 100; higher scores indicating higher levels of dysfunction) Participant-reported 3rd interval (4 weeks after surgery)</p> <p><i>Postoperative mental distress</i> Mental health Short form health survey-36 (SF-36), mental health sub scale Continuous measure (5 items, higher scores indicating better mental health) Participant-reported 3rd interval (4 weeks after surgery)</p> <p><i>Postoperative pain intensity</i> Pain Short form health survey-36 (SF-36), sub scale bodily pain Continuous measure (2 items, higher scores indicating lower levels of pain) Participant-reported 3rd interval (4 weeks after surgery)</p>

	No adverse events reported.	
Notes	Sources of funding: not reported Conflicts of interests: not reported	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	“Patients selected by random sampling method” (p. 320), “Initially, we selected the experimental group, and then the control group.” (p. 320)
Allocation concealment (selection bias)	High risk	Allocation based on blockwise alternation
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	High risk	Numbers of missing data balanced across groups, but reasons not stated
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Ku 2002**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<i>Setting</i> Taipei Veterans General Hospital, Taiwan  <i>Inclusion criteria</i> Older than 40 years Elective coronary artery bypass surgery Able to understand Mandarin and/or Taiwanese, able to read Chinese or with interpreter <i>Exclusion criteria</i> Previous open heart surgery

	Known neurologic problem <i>Baseline data</i> N = 60 (intervention 30, control 30) Male gender: 83% (intervention 87%; control 80%) Mean age: intervention 68.5 years; control 69 years Married: intervention 97%; control 80% Education ≥ 12 years: both groups 47% Employed: intervention 10%; control 13%	
Interventions	<i>Routine care for all participants</i> Regular preoperative nursing care 1 day before surgery by the ward nurse  <i>Attention control group</i> Daily social visit by the researcher (10 mins every afternoon) during hospitalisation; researcher was recording exercises and daily activities  <i>Intervention group</i> Psychoeducation Phase I cardiac rehabilitation Chinese manual Brochure with illustrations of indications and contraindications of cardiac rehabilitation, general principles of exercise prescription, exercise programmes; daily activities programme given to the participants preoperatively; researcher discussed participant’s concerns and questions, and recorded exercises and daily activities, 15 mins every afternoon during hospitalisation	
Outcomes	<i>Postoperative mental distress</i> Anxiety State-Trait Anxiety Inventory (STAI, Chinese version), state anxiety score Continuous measure (score ranges from 20 - 80; higher scores indicate higher anxiety) Participant-reported 2nd interval (at discharge) No adverse events reported.	
Notes	Sources of funding: not reported Conflicts of interests: not reported	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	High risk	“Subjects were randomly assigned” (p. 135) , “A quasi-experimental study design was used” (p.134)
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described

Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Mahler 1998**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<p><i>Setting</i> Scripps Memorial Hospital and San Diego Veterans Affairs Center in La Jolla, California, USA</p> <p><i>Inclusion criteria</i> First time, nonemergency coronary artery bypass surgery without associated procedures (e.g. valve surgery) Male gender English speaking</p> <p><i>Exclusion criteria</i> Serious medical problems (e.g., terminal cancer)</p> <p><i>Baseline data</i> N = 258 (no information about initial distribution across groups) Coronary artery bypass surgery (mean number of grafts: 3.8; ejection fraction: 57%) Male gender: 100% Mean age: 62.5 years Married: 75% Education: 13.5 years</p>
Interventions	<p><i>Routine care for all participants</i> Standard discharge preparation, consisting almost exclusively of procedural information (e.g., basic information regarding how the surgery is performed, length of typical stay in the ICU and hospital) and instructions regarding performance of recovery behaviours (e.g., deep breathing and coughing, ambulation), orally provided by a nurse or by commercially-prepared videotapes (e.g. 5-min video how to use the incentive spirometer)</p> <p><i>Control group</i> Routine care (TAU)</p>

	<i>Intervention groups</i> Group A) Psychoeducation “Mastery tape” provides excerpts of interviews with 3 male CABG patients the day prior to surgery and several days after surgery; videotaped patients were discussing their own experiences/feelings and were not coached; patients were depicted as relatively calm preoperatively and as overcoming difficulties of surgery rather easily by making steady progress postoperatively; video was provided on the evening prior to surgery  Group B) Psychoeducation “Coping tape” provides excerpts of interviews with 3 male CABG patients the day prior to surgery and several days after surgery; videotaped patients were discussing their own experiences/feelings and were not coached; patients were depicted as coping effortfully but successfully with a variety of postoperative difficulties; was provided on the evening prior to surgery  Group C) Psychoeducation “Nurse tape” features only narration and demonstrations by a cardiothoracic nurse specialist; was provided on the evening prior to surgery	
Outcomes	<i>Postoperative levels of mobility</i> Postoperative ambulation Integrated Motor Activity Monitor counting movements by means of a miniature mercury switch that is sensitive to 10° of tilt off horizontal, worn for an average of 7.55 hours each recording day Continuous measure (counted movements; higher scores indicate greater ambulation) Observer-reported 2nd interval (2nd to 5th postoperative day) No adverse events reported.	
Notes	Sources of funding: grants by the American Heart Association and the National Heart, Lung, and Blood Institute Conflicts of interests: not reported	
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Observer-reported outcomes	Unclear risk	Mobility: no information about blinding of outcome assessors

**Mahler 1998** (Continued)

Incomplete outcome data (attrition bias) short-term	Unclear risk	No information about initial distribution across groups, only number of analysed participants given
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Mahler 1999**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<p><i>Setting</i> Scripps Memorial Hospital and San Diego Veterans Affairs Center in La Jolla, California, USA</p> <p><i>Inclusion criteria</i> First-time, nonemergency coronary artery bypass surgery</p> <p><i>Exclusion criteria</i> Not described</p> <p><i>Baseline data</i> N = 215 (intervention A (mastery tape) 65, intervention B (coping tape) 75, control 75) Coronary artery bypass surgery (mean number of grafts: 4, ejection fraction: 53%) Male gender: 86.5% Mean age: 61.4 years Married: 82% Education: 14.2 years</p>
Interventions	<p><i>Routine care for all participants</i> Standard discharge preparation</p> <p><i>Control group</i> Routine care (TAU)</p> <p><i>Intervention groups</i> Group A) Psychoeducation “Mastery tape” providing accurate procedural information (e.g., instructions regarding lifting, exercise, diet, incision care, resumption of normal activities, when to get medical attention) and sensory information (e.g., levels of pain and fatigue common at various points after surgery, common emotions, sleep and appetite changes), narration by cardiothoracic nurse specialist, videotaped patients, not coached, depicted as calm and confident at the time of release, as making steady progress with no mention of complications during 6 months after surgery, as adjusting to the recommended exercise and low-fat diet with relative ease; was provided on the evening prior to surgery</p>

	Group B) Psychoeducation “Coping tape” providing accurate procedural information and sensory information (see A for details), narration by cardiothoracic nurse specialist, videotaped patients, not coached, mention concerns they are experiencing about hospital release and cope with effort but successful with a variety of difficulties (e.g., heart rhythm disturbances, fatigue, diet changes); was provided on the evening prior to surgery	
Outcomes	<i>Postoperative mental distress</i> Anxiety Positive and Negative Affect Schedule (PANAS, <a href="#">Watson 1988</a> ), anxiety items Continuous measure (average of 6 items measured on 5-point scale; higher scores indicate greater anxiety) Participant-reported 2nd interval (at discharge) 3rd interval (1 month after discharge/3 months after discharge) No adverse events reported.	
Notes	Sources of funding: grant by the National Heart, Lung, and Blood Institute Conflicts of interests: not reported	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors’ judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	High risk	Imbalance in numbers for missing data across intervention groups, no reasons for missing data stated
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

Methods	<p>Randomised controlled trial</p> <p>Study duration: 4 months</p> <p>Date study was conducted: February 2010 - June 2010</p>
Participants	<p><i>Setting</i></p> <p>Cardiac surgery unit, Hospital Centre of the University of Montreal, Canada</p> <p><i>Inclusion criteria</i></p> <p>18 years and older</p> <p>First intention cardiac surgery involving sternotomy (coronary artery bypass surgery, valve replacement, or both procedures)</p> <p>Able to understand and complete questionnaires in French</p> <p><i>Exclusion criteria</i></p> <p>Previous cardiac surgery</p> <p>Patients planned to be on a postoperative epidural protocol</p> <p>Unable to consent because of a cognitive or psychiatric disorder</p> <p><i>Baseline data</i></p> <p>N = 52 (intervention 30, control 30)</p> <p>Coronary artery bypass surgery 60%, valve replacement 17%, both procedures 21% (mean number of grafts: intervention 3.3; control 2.5)</p> <p>Male gender: intervention 80%; control 77%</p> <p>Mean age: intervention 64.6 years; control 63.2 years</p> <p>Married: intervention 70%; control 64%</p> <p>High school education or university: intervention 45%; control 53%</p> <p>Working (full time/part time): intervention 45%; control 47%</p>
Interventions	<p><i>Routine care for all patients</i></p> <p>Pamphlet describing general principles of pain management</p> <p><i>Control group</i></p> <p>Routine care (TAU)</p> <p><i>Intervention group</i></p> <p>Psychoeducation</p> <p>SOULAGE-TAVIE web application (French version of self-managment support-treatment-virtual nursing assistance and education)</p> <p>one day/few days before surgery: 30-min tailored preoperative session on laptop animated by a virtual nurse that guides the participant through a learning process about management of pain; 2nd and 3rd postoperative day: 5 - 10-min tailored reinforcements with principal investigator</p>
Outcomes	<p><i>Postoperative mental distress</i></p> <p>Anxiety</p> <p>Hospital Anxiety and Depression Scale (HADS, <a href="#">Zigmond 1983</a>) - anxiety sub scale</p> <p>Continuous measure (higher scores indicate higher anxiety)</p> <p>Participant-reported</p> <p>2nd interval (day 7 after surgery)</p> <p><i>Postoperative mental distress</i></p> <p>Depression</p>



	<p>Hospital Anxiety and Depression Scale (HADS, <a href="#">Zigmond 1983</a>) - depression sub scale Continuous measure (higher scores indicate higher depression) Participant-reported 2nd interval (day 7 after surgery)</p> <p><i>Postoperative pain intensity</i> Present pain Numeric rating scale (NRS) Continuous measure (0 = no pain at all, 10 = worst possible pain) Participant-reported 1st interval (24-hour postoperatively/48-hour postoperatively) 2nd interval (day 7 after surgery)</p> <p><i>Postoperative pain intensity</i> Average pain upon last 24 hours Numeric rating scale (NRS) Continuous measure (0 = no pain at all, 10 = worst possible pain) Participant-reported 1st interval (24-hour postoperatively/48-hour postoperatively) 2nd interval (day 7 after surgery)</p> <p><i>Postoperative pain intensity</i> Worst pain upon last 24 hours Numeric rating scale (NRS) Continuous measure (0=no pain at all, 10=worst possible pain) Participant-reported 1st interval (24h postoperatively/48h postoperatively) 2nd interval (day 7 after surgery)</p> <p><i>Postoperative pain intensity</i> Present pain at rest Numeric rating scale (NRS) Continuous measure (0 = no pain at all, 10 = worst possible pain) Participant-reported 1st interval (24h postoperatively/48h postoperatively) 2nd interval (day 7 after surgery)</p> <p><i>Postoperative analgesic use (PCA)</i> Opioid dose (morphine equivalents) Continuous measure (higher levels indicate higher dose) Observer-reported 1st interval (24-hour postoperatively/48-hour postoperatively) 2nd interval (day 7 after surgery) No adverse events reported.</p>
Notes	<p>Sources of funding: grants from the Quebec Interuniversity Nursing Intervention Research Group (Groupe de recherche interuniversitaire sur les interventions en sciences infirmières du Québec; GRIISIQ), the Canadian Nurses Foundation (CNF), and the Chair for Research Into New Practices in Nursing of the CHUM which is held by Dr José Côté. doctoral fellowship from Canadian Institutes of Health Research (CIHR)</p>

No conflict of interest declared by the authors		
<b><i>Risk of bias</i></b>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Permuted-block randomization with allocation ratio of 4 was used to generate a list through computer software" (p.7 of manuscript retrieved by study author)
Allocation concealment (selection bias)	Low risk	"The randomized allocation through the use of concealed envelopes was also clarified." (p.7)
Blinding of medical personnel (performance bias)	Low risk	"Clinical staff was blinded to group allocation." (p.8)
Blinding of outcome assessment (detection bias) Observer-reported outcomes	Low risk	Postoperative analgesic use (PCA): "medical records that were examined by a trained nurse who was also blinded to group allocation" (p.7)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Self-reported outcomes
Incomplete outcome data (attrition bias) short-term	Low risk	"The protocol privileged an intention-to-treat approach for the analysis of results" (p.17)
Selective reporting (reporting bias)	Low risk	Study protocol available (ClinicalTrials.gov Identifier:NCT01084018)

**Moore 2001**

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: not reported
Participants	<i>Setting</i> Cardiac unit at an 800-bed acute-care urban teaching hospital in Cleveland, Ohio, USA  <i>Inclusion criteria</i> Having had first coronary artery bypass surgery within the last 4 or 5 days Being cognitively intact being able to speak, read and write English Residing within a 90-mile radius of Cleveland

	Being discharged to one’ s home <i>Exclusion criteria</i> Having major complications from surgery <i>Baseline data</i> N = 180 (intervention 90, control 90) Coronary artery bypass surgery (mean number of grafts intervention: 3.3; control: 3.5) Male gender: 53% Mean age: intervention 62 years; control 63 years Married: intervention 71%; control 62% Education: intervention 12.8 years; control 13.5 years Employed: intervention 51%; control 41% NYHA III+IV: intervention 42%; control 41%	
Interventions	<i>Routine care for all participants</i> Usual discharge instructions provided by unit nurses consisting of information about cardiac physiology, risk factor modification, activity, diet guidelines, medications, and general recovery information in form of videotapes, pamphlets, and one-to-one counselling <i>Control group</i> Routine care (TAU)  <i>Intervention group</i> Psychoeducation Cardiac Home Information Program (CHIP, Moore 1994) 15-min audiotaped message with a professional female voice, describes typical recovery experiences of CABG patients, participants listened once at hospital (4th/5th postop. day) under observation of research assistant, encouraged to listen to the audiotape as many times as they felt necessary at hospital and at home	
Outcomes	<i>Postoperative mental distress</i> Psychological distress/ Psychological functioning Profile of Mood States (POMS, McNair 1971) - total score Continuous measure (sum of 43 items measured on 5-point scale ranging from 1 = not at all to 5 = extremely; higher scores indicate greater distress) Participant-reported 3rd interval (1 month after discharge) No adverse events reported.	
Notes	Sources of funding: American Heart Association (grant number: 96009410) Conflicts of interests: not reported	
<i>Risk of bias</i>		
Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Table of random numbers was used, p. 98

**Moore 2001** (Continued)

Allocation concealment (selection bias)	Unclear risk	"A sealed envelope indicating group assignment (determined using a table of random numbers) was opened by the RA" (p. 98); unclear if envelopes were sequentially numbered and opaque
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	Numbers of participants who did not complete and reasons stated, numbers of participants who dropped out equally distributed between intervention and control groups
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Parent 2000**

Methods	Randomised controlled trial Study duration: 4 months Date study was conducted: June 2004 - September 2004
Participants	<p><i>Setting</i> Montreal Heart Institute, Quebec, Canada</p> <p><i>Inclusion criteria</i> Age 40 to 69 years First-time elective coronary artery bypass surgery Male gender</p> <p><i>Exclusion criteria</i> Valve dysfunction, signs or symptoms of unstable arrhythmias or heart failure History of or treatment for psychiatric illness</p> <p><i>Baseline data</i> N = 67 (intervention 36, control 31) Coronary artery bypass surgery (median number of grafts: 3) Male gender: 100% Mean age: intervention 57.6 years; control 55.9 years Previous myocardial infarction: intervention 37%; control 36%</p>

Interventions	<p><i>Routine care for all patients</i> Routine information on surgery and recovery by health professionals</p> <p><i>Control group</i> Routine care (TAU)</p> <p><i>Intervention group</i> Psychoeducation One-on-one support intervention, 3 supporting visits by a volunteer former patient (trained), providing vicarious experience, emotional and informational support to reassure participants, coach them toward activity, and reinforce risk factor reduction; supportive acts included listening, responding to concerns, affirmation, feedback, and social comparisons; interventions were tailored to the participant's needs 24 hours before surgery, 5th postoperative day, 4 weeks after surgery</p>
Outcomes	<p><i>Postoperative mental distress</i> Anxiety State Trait Anxiety Inventory (STAI, French version, <a href="#">Bergeron 1976</a>) -state anxiety Continuous measure (20 items; total scores ranging from 20 - 80; higher scores indicate greater anxiety) Participant-reported 3rd interval (5th postoperative day, 4 weeks after discharge)</p> <p><i>Postoperative levels of mobility</i> Walking Jenkins Activity Checklist (<a href="#">Jenkins 1989</a>) - sub scale walking Continuous measure (3-point scale checklist, ratings of yes/no/not applicable, for carrying out each physical activity in the previous 24 hours, total score by summing up number of yes-responses; scale ranges from 0 - 14 for walking; higher scores indicate higher reported performance of activity) Participant-reported 3rd interval (5th postoperative day, 4 weeks after discharge)</p> <p><i>Postoperative levels of mobility</i> Climbing Jenkins Activity Checklist (<a href="#">Jenkins 1989</a>) - sub scale climbing Continuous measure (3-point scale checklist, ratings of yes/no/not applicable, for carrying out each physical activity in the previous 24 hours, total score by summing up number of yes-responses; scale ranges from 0 - 7 for climbing; higher scores indicate higher reported performance of activity) Participant-reported 3rd interval (5th postoperative day, 4 weeks after discharge)</p> <p><i>Postoperative levels of mobility</i> General activities Jenkins Activity Checklist (<a href="#">Jenkins 1989</a>) - total activity score Continuous measure (3-point scale checklist, ratings of yes/no/not applicable, for carrying out each physical activity in the previous 24 hours, total score by summing up number of yes-responses; higher scores indicate higher reported performance of activity)</p>

**Parent 2000** (Continued)

	Participant-reported 3rd interval (5th postoperative day, 4 weeks after discharge) No adverse events reported.	
Notes	Sources of funding: none Conflicts of interests: not reported	
<b><i>Risk of bias</i></b>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	Randomisation by flipping a coin
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	High risk	Numbers of missing data imbalanced across groups
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Parthum 2006**

Methods	Randomised controlled trial Study duration: 7 months Date study was conducted: February 2004 - August 2004	
Participants	<i>Setting</i> University hospital, Germany  <i>Inclusion criteria</i> Older than 18 years First-time coronary artery bypass surgery (CABG), valve surgery, or combined CABG + valve surgery German patients, conversant in German <i>Exclusion criteria</i>	

	<p>Emergency surgery</p> <p>Previous heart surgery</p> <p>Regular pain medication preoperatively</p> <p>Postoperative intubation longer than 24 hours</p> <p>Intensive care stay longer than 72 hours after extubation</p> <p>Psychiatric disorders, dementia, or disorientation</p> <p><i>Baseline data</i></p> <p>N = 93 (intervention 45, control 48)</p> <p>No further baseline data described</p>
Interventions	<p><i>Routine care for all patients</i></p> <p>Not described</p> <p><i>Control group</i></p> <p>Routine care (TAU)</p> <p><i>Intervention group</i></p> <p>Psychoeducation</p> <p>Individual preoperative participant education about postoperative pain and pain management (development of postoperative pain, pain perception, consequences, therapy) on the evening before surgery</p> <p>Duration about 20 mins</p> <p>Participants also received an information leaflet</p>
Outcomes	<p><i>Postoperative pain intensity</i></p> <p>Pain during rest retrospective with regard to ICU stay</p> <p>VAS</p> <p>Dichotomous measure (number of participants with VAS <math>\leq 3</math>)</p> <p>Participant-reported</p> <p>1st interval (36 hours postoperatively)</p> <p><i>Postoperative pain intensity</i></p> <p>Pain under stress retrospective with regard to ICU stay</p> <p>VAS</p> <p>Dichotomous measure (number of participants with VAS <math>\leq 3</math>)</p> <p>Participant-reported</p> <p>1st interval (36 hours postoperatively)</p> <p><i>Postoperative pain intensity</i></p> <p>Present pain during rest</p> <p>VAS</p> <p>Dichotomous measure (number of participants with VAS <math>\leq 3</math>)</p> <p>Participant-reported</p> <p>1st interval (36 hours postoperatively)</p> <p><i>Postoperative pain intensity</i></p> <p>Present pain under stress</p> <p>VAS</p> <p>Dichotomous measure (number of participants with VAS <math>\leq 3</math>)</p>

**Parthum 2006** (Continued)

	Participant-reported 1st interval (36 hours postoperatively) No adverse events reported.	
Notes	Sources of funding: not reported No conflict of interest declared by the authors	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	High risk	Computer-generated random numbers, but randomisation based on day of hospital admission
Allocation concealment (selection bias)	High risk	Randomisation based on day of hospital admission
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	Balanced numbers and reasons of missing data across groups
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Pick 1994**

Methods	Randomised controlled trial Study duration: 18 months Date study was conducted: not reported	
Participants	<i>Setting</i> London teaching hospital, UK  <i>Inclusion criteria</i> Elective coronary artery bypass surgery <i>Exclusion criteria</i> Surgery in addition to coronary artery bypass	



	<p>Non-standard anaesthetic technique</p> <p><i>Baseline data</i></p> <p>N = 74 (intervention 25, control A (TAU) 24, control B (emotional support) 25)</p> <p>Male gender: intervention 84%; control 88%</p> <p>Mean age: intervention 58 years; control A 61 years; control B 56 years</p>
Interventions	<p><i>Routine care for all participants</i></p> <p>Not described</p> <p><i>Control groups</i></p> <p>Group A) Routine care (TAU)</p> <p>Group B) Attention control group</p> <p>On the day before surgery: participants were visited by the researcher according to the same schedule as the intervention group, were prompted to express their worries and feelings about their hospitalisation and surgery, researcher reflected these concerns, demonstrated that she understood them and accepted them as neutral, emphasised her own concerns for the participant's wellbeing; 2 hours after arrival in ICU when awakening from anaesthesia participants were played an audiotape of the researcher's voice reassuring them that the operation was complete and that they should simply let the staff do everything to care for them</p> <p><i>Intervention group</i></p> <p>Relaxation</p> <p>Visit by researcher on the day before surgery before premedication and twice during first 36 hours postoperatively, each visit lasted about 30 mins, participants were instructed in a relaxation technique based on progressive muscle relaxation, but without instructions for muscle tensing, participants practised breathing through an intubation tube, were encouraged to feel that they would have control over their own ventilation postoperatively, practised using relaxation to facilitate this and to overcome the feelings of discomfort and nausea; 2 hours after arrival in ICU when awakening from anaesthesia audiotape with same instructions played</p>
Outcomes	<p><i>Postoperative mental distress</i></p> <p>Anxiety</p> <p>Zung Anxiety and Depression Scale (Zung 1974), sub scale anxiety</p> <p>Continuous measure (higher scores indicate greater anxiety)</p> <p>Participant-reported</p> <p>1st interval (1 day after surgery)</p> <p>3rd interval (30 days after discharge)</p> <p><i>Postoperative mental distress</i></p> <p>Depression</p> <p>Zung Anxiety and Depression Scale (Zung 1974), sub scale depression</p> <p>Continuous measure (higher scores indicate greater depression)</p> <p>Participant-reported</p> <p>1st interval (1 day after surgery)</p> <p>3rd interval (30 days after discharge)</p> <p>No adverse events reported.</p>

**Pick 1994** (Continued)

Notes	Sources of funding: grant from the British Heart Foundation Conflicts of interests: not reported	
<i>Risk of bias</i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	High risk	No reasons for attrition stated, “79% returned completed questionnaires 30 days postoperatively”, p. 601
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Shelley 2007**

Methods	Randomised controlled Study duration: not reported Date study was conducted: not reported
Participants	<i>Setting</i> Not described  <i>Inclusion criteria</i> First-time coronary artery bypass patients <i>Exclusion criteria</i> Previously received invasive treatments for heart disease Unable to give legal informed consent Outside the age range of 30-90 years Received immunization within the past 2 years Suffered an immune-related disease (such as autoimmune disease, HIV, or hepatitis)

	Taking hormone replacements <i>Baseline data</i> N = 80 (intervention 37, control 43) Male gender: intervention 59%; control 72% Mean age: intervention 65.1 years; control 66.1 years	
Interventions	<i>Routine care for all patients</i> Not described  <i>Control group</i> Routine care (TAU) <i>Intervention group</i> Psychoeducation, Cognitive-behavioural intervention Preparation designed to aid learning of hospital procedural information and address participant thoughts about how to deal with health-related concerns; four stages: building rapport, participant concerns, question prompts, linking questions with concerns Duration about 30 mins, in the evening of the day before surgery Conducted by research psychologist	
Outcomes	<i>Postoperative mental distress</i> Distress Depression, Anxiety, and Stress Scales (DASS, <a href="#">Lovibond 1995</a> ), short form, total score Continuous measure (sum of 21 items measured on 4-point scale ranging from 0 = did not apply to me at all to 4 = applied to me very much; higher scores indicate greater distress) Participant-reported 2nd interval (at discharge) 3rd interval (12 months follow-up after discharge)  <i>Postoperative pain intensity</i> Present pain VAS, linear 10-cm scale Continuous measure (no pain to pain as bad as it could be) Participant-reported 2nd interval (at discharge) 3rd interval (12 months follow-up after discharge) No adverse events reported.	
Notes	12 month follow-up data for distress and pain intensity were provided by Dr. Mike Shelley (personal communication) Sources of funding: grant from the Wesley Research Institute Conflicts of interests: not reported	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described

**Shelley 2007** (Continued)

Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Low risk	“the RA administered all inventories, and the data produced and assignments were not revealed to patients, the psychologist, or other hospital staff until the conclusion of the study” (p. 186)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Unclear risk	Not described
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Sørli 2007**

Methods	Randomised controlled trial Study duration: 58 months Date study was conducted: September 1998 - June 2003
Participants	<p><i>Setting</i> Department of Cardiothoracic and Vascular Surgery at the University Hospital of North Norway</p> <p><i>Inclusion criteria</i> Age less than 68 years Stable angina with a planned first-time coronary artery bypass surgery</p> <p><i>Exclusion criteria</i> Severe comorbidity Severe cognitive impairment Transferred from other kinds of medical treatment or care</p> <p><i>Baseline data</i> N = 109 (intervention 55, control 54) Male gender: intervention 89%; control 87% Mean age: intervention 59 years; control 57.5 years Married or cohabiting: intervention 91%; control 85% Education: intervention 9 years; control 8.3 years Working or at sick leave: intervention 58%; control 54%</p>

Interventions	<p><i>Routine care for all participants</i></p> <p>Usual routine hospital pre- and postoperative information</p> <p>First session at admission: information on a checklist including procedural and sensory information related to the major diagnostic and pre- and postoperative events during hospital stay, some behavioural instructions</p> <p>Second session at hospital discharge: information on preventive life style changes and mastering the situation at home and at work</p> <p>Each session 40 mins duration, carried out by several different nurses</p> <p><i>Control group</i></p> <p>Routine care (TAU)</p> <p><i>Intervention group</i></p> <p>Psychoeducation, Cognitive-behavioural intervention</p> <p>12-min video viewed at home prior to the hospital admission and during the first information session on admission, illustrates the most important events during hospital treatment and aftercare, presented as a dialogue between a recently discharged patient and a friend, to give some familiarity with the treatment situation and to stimulate curiosity and information-seeking among participants</p> <p>Two information sessions of 40 mins with specially trained nurses; on admission and at hospital discharge, providing relevant information and support to enhance participants' self regulation and capacity for co-operation with the healthcare professional</p>
Outcomes	<p><i>Postoperative mental distress</i></p> <p>Anxiety</p> <p>Beck Anxiety Inventory (BAI, Beck 1988) - total score</p> <p>Continuous measure (sum of 21 items, score ranges from 21 - 84; higher scores indicate greater anxiety)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (2 weeks after discharge, 6 weeks after discharge, 6 months after discharge, 1 year after discharge, 2 years after discharge)</p> <p><i>Postoperative mental distress</i></p> <p>Depression</p> <p>Zung self-rating depression scale (Zung 1965) - total score</p> <p>Continuous measure (sum of 20 items, score ranges from 20 - 80; higher scores indicate greater depression)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (2 weeks after discharge, 6 weeks after discharge, 6 months after discharge, 1 year after discharge, 2 years after discharge)</p> <p>No adverse events reported.</p>
Notes	<p>Sources of funding: North Norwegian Psychiatric Research Center</p> <p>Conflicts of interests: not reported</p>
<i>Risk of bias</i>	

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"Each patient in each block of 20 consecutively consenting patients, were randomly assigned..." (p. 182)
Allocation concealment (selection bias)	Low risk	"Each patient [...] were randomly assigned by using opaque, sealed, and sequentially numbered envelopes to either the intervention or the control group status." (p. 182)
Blinding of medical personnel (performance bias)	Low risk	"The treating physicians were blinded to the assignment group." (p. 182)
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	"All patients in the study sample (N=109) were analysed at all timepoints ("last observation carried forward analysis")." (p. 183)
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

#### Utriyaprasit 2010

Methods	Randomised controlled trial Study duration: not reported Date study was conducted: 2004 - 2005
Participants	<p><i>Setting</i> Cardiac unit in a tertiary centre in Thailand</p> <p><i>Inclusion criteria</i> 18 years or older First coronary artery bypass surgery within the last 8 or 9 days Mentally competent Literate in Thai language</p> <p><i>Exclusion criteria</i> Surgery for cardiac valve repair, Major complications from surgery, including cardiac arrest, pulmonary emboli and haemorrhage</p>

	<p><i>Baseline data</i></p> <p>N = 120 (intervention 60, control 60)</p> <p>Coronary artery bypass surgery (ejection fraction: intervention 58%; control 65%; mean number of grafts intervention 3.8; control 3.7)</p> <p>Male gender: 70%</p> <p>Mean age: intervention 62.8 years; control 63.3 years</p> <p>Married: intervention 83%; control 82%</p> <p>Education: intervention 7.7 years; control 10.9 years</p> <p>NYHA III: intervention 17%; control 15%</p>
Interventions	<p><i>Routine care for all participants</i></p> <p>Usual cardiac teaching and discharge instructions (before surgery together with relatives: information about the physiology of the heart, CABG procedure, care team, care instructions before and after surgery; day before discharge: information about risk factor modification, activity, diet guidelines, homegoing medication provided by unit nurses)</p> <p><i>Attention control group</i></p> <p>Visit from researcher on 8th or 9th postoperative day, telephone call 2 weeks and 4 weeks after hospital discharge; general questions about health and wellbeing</p> <p><i>Intervention group</i></p> <p>Psychoeducation, Relaxation</p> <p>Cardiac Home Information Program, modified Thai version (Thai CHIP) (CHIP: <a href="#">Moore 1994</a>)</p> <p>30-min audiotaped message with a male voice, containing the expected recovery experiences in sensory and temporal terms and suggestions for coping with them, added by deep breathing relaxation and active progressive relaxation technique, participants listened once at hospital (8th/9th postop. day) under supervision, encouraged to listen to the audiotape as many times as they felt necessary at hospital and at home</p>
Outcomes	<p><i>Postoperative pain intensity</i></p> <p>Pain/discomfort</p> <p>Cardiac Surgery Symptom Inventory (SI, <a href="#">Artinian 1993</a>), sub scale shoulder, back or neck pain/discomfort</p> <p>Continuous measure (scale from 1 - 7 for the frequency of symptoms; higher scores indicate more symptoms)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (2 weeks after discharge, 4 weeks after discharge)</p> <p><i>Postoperative levels of mobility</i></p> <p>Ambulation</p> <p>Sickness Impact Profile (SIP, <a href="#">Bergner 1981</a>), physical scale, sub scale ambulation</p> <p>Continuous measure (higher scores indicate greater physical dysfunction)</p> <p>Participant-reported</p> <p>2nd interval (at discharge)</p> <p>3rd interval (2 weeks after discharge, 4 weeks after discharge)</p> <p><i>Postoperative levels of mobility</i></p>

	Mobility Sickness Impact Profile (SIP, <a href="#">Bergner 1981</a> ), physical scale, sub scale mobility Continuous measure (higher scores indicate greater physical dysfunction) Participant-reported 2nd interval (at discharge) 3rd interval (2 weeks after discharge, 4 weeks after discharge)  <i>Postoperative mental distress</i> Psychological distress/Psychological functioning Profile of Mood States (POMS, <a href="#">McNair 1971</a> ), total score Continuous measure (sum of 43 items measured on 5-point scale ranging from 0 = not at all to 4 = extremely; higher scores indicate greater distress) Participant-reported 2nd interval (at discharge) 3rd interval (2 weeks after discharge, 4 weeks after discharge) No adverse events reported.	
Notes	Sources of funding: Thailand Research Fund (grant no.: TRG 4580030) No conflict of interest declared by the authors	
<i><b>Risk of bias</b></i>		
<b>Bias</b>	<b>Authors' judgement</b>	<b>Support for judgement</b>
Random sequence generation (selection bias)	Low risk	"Randomization minimization computer program was used to determine group assignment maintaining group balance in terms of gender, NYHA class and surgeon" (p. 1750)
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described
Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	Low risk	Numbers of participants who did not complete reported and reasons stated, numbers of participants who dropped out equally distributed between intervention and control groups
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to



		compare outcomes of the protocol and reported outcomes
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**Zarani 2010**

Methods	Randomised controlled trial Study duration: 5 months Date study was conducted: April 2007 - August 2007
Participants	<p><i>Setting</i> Teheran Heart Center, Iran</p> <p><i>Inclusion criteria</i> Age between 40 and 65 years Coronary artery bypass surgery Diagnosis of a heart problem for &gt;1 years Absence of comorbidities Ability to read and write Absence of visual/hearing impairment Access to medical care</p> <p><i>Exclusion criteria</i> Not described</p> <p><i>Baseline data</i> N = 152 (intervention 75, control 77) Male gender: intervention 83%; control 81% Mean age: 53.2 years Married: intervention 99%; control 97% Lower education (high school or less): intervention 75%; control 85%</p>
Interventions	<p><i>Routine care for all patients</i> Not described</p> <p><i>Attention control group</i> Combination of medical treatment, physician monitoring, and group classes about risk factors for coronary heart disease and self-care behaviours after surgery + supportive counselling</p> <p><i>Intervention group</i> Psychoeducation, Cognitive-behavioural intervention Preoperative Information-Motivation-Behavioural (IBM) skills model of health behavioural change intervention (Fisher 2003). Information component: participants received information about heart disease risk factors and adherence behaviours using a variety of teaching aids (short educational film, handouts) Motivational component: help for participants to identify, verbalise, and reinforce positive attitudes and behavioural skills deficits by using motivational interview techniques (providing personal feedback, asking open-ended questions, affirmations, reflective listening etc.) to enhance personal and social motivation to adherence to medical recommendations</p>

	Behavioural skills component: teaching how to effectively monitor nutrition, integrate physical activity into lifestyle, quit smoking, control stress, and to self-administer medications 1 session 120 mins, group intervention (5 participants)	
Outcomes	<i>Postoperative mental distress</i> Anxiety Hospital Anxiety and Depression Scale (Iranian version, <a href="#">Montazeri 2003</a> ) - anxiety sub scale Continuous measure (sum of 7 items measured on 4-point scale, scores range from 0 - 21; higher scores indicate greater anxiety) Participant-reported 3rd interval (1 month after surgery)  <i>Postoperative mental distress</i> Depression Hospital Anxiety and Depression Scale (Iranian version, <a href="#">Montazeri 2003</a> ) - depression sub scale Continuous measure (sum of 7 items measured on 4-point scale, scores range from 0 - 21; higher scores indicate greater depression) Participant-reported 3rd interval (1 month after surgery)  <i>Postoperative mental distress</i> Stress Perceived Stress Scale (PSS, <a href="#">Cohen 1983</a> ) Continuous measure (sum of 10 items measured on 4-point scale, scores range from 0 - 40; higher scores indicate greater stress) Participant-reported 3rd interval (1 month after surgery) No adverse events reported.	
Notes	Sources of funding: not reported No conflict of interest declared by the authors	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of medical personnel (performance bias)	Unclear risk	Not described

Blinding of outcome assessment (detection bias) Participant-reported outcomes	Unclear risk	Participant-reported outcome
Incomplete outcome data (attrition bias) short-term	High risk	Number of missing data balanced, reasons for missing data stated but not separately for groups
Selective reporting (reporting bias)	Unclear risk	No discrepancies between outcomes listed in the methods section and outcomes reported in the results section of the trial, however, study protocol is not available to compare outcomes of the protocol and reported outcomes

**Characteristics of excluded studies [ordered by study ID]**

Study	Reason for exclusion
Ashton 1997	Sample size fewer than 20 participants in each group at first postoperative assessment
Blankfield 1995	Participants were recruited regardless of whether or not the surgery was elective or nonelective
Cupples 1991	Preadmission intervention (intervention provided before admission to hospital)
Hartford 2002	Postdischarge intervention (intervention began on day of discharge and was provided almost exclusively after discharge)
Hermele 2005	Preadmission intervention (intervention provided before admission to hospital)
Houston 1999	Sample size fewer than 20 participants in each group at first postoperative assessment
Hwang 1998	Participants under 18 years of age were recruited
Ikedo 2007	Intervention was not eligible (Hemi-Sync audiotape)
Lamarche 1998	Preadmission intervention (intervention provided before admission to hospital)
Postlethwaite 1986	Sample size fewer than 20 participants in each group at first postoperative assessment
Shuldham 2002	Preadmission intervention (intervention provided before admission to hospital)
Stein 2010	Sample size fewer than 20 participants in each group at first postoperative assessment

(Continued)

Thoits 2000	Intervention was not eligible (similar-other support: former patients trained in supportive techniques visit the participants and perform minor within-hospital favours for participants)
Watt-Watson 2000	Sample size fewer than 20 participants in each group at first postoperative assessment
Watt-Watson 2004	Preadmission intervention (intervention provided before admission to hospital)
Yin 2011	Open heart surgery patients were not recruited (personal communication)

## DATA AND ANALYSES

### Comparison 1. Psychological intervention vs control condition

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain intensity measured with continuous scales: medium-term	4	413	Hedges' g (Random, 95% CI)	-0.02 [-0.24, 0.20]
2 Pain intensity measured with continuous scales: long-term	3	280	Hedges' g (Random, 95% CI)	0.12 [-0.09, 0.33]
3 Mental distress: medium-term	12	1144	Hedges' g (Random, 95% CI)	0.36 [0.10, 0.62]
4 Mental distress: long-term	11	1320	Hedges' g (Random, 95% CI)	0.28 [0.05, 0.51]
5 Mobility: medium-term	3	444	Hedges' g (Random, 95% CI)	0.23 [-0.22, 0.67]
6 Mobility: long-term	4	423	Hedges' g (Random, 95% CI)	0.29 [-0.14, 0.71]

### Comparison 2. Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Pain intensity measured with continuous scales: medium-term	3	293	Hedges' g (Random, 95% CI)	0.09 [-0.11, 0.29]
2 Pain intensity measured with continuous scales: long-term	2	160	Hedges' g (Random, 95% CI)	0.18 [-0.11, 0.46]
3 Mental distress: medium-term	9	904	Hedges' g (Random, 95% CI)	0.34 [0.03, 0.64]
4 Mental distress: long-term	9	986	Hedges' g (Random, 95% CI)	0.37 [0.11, 0.63]
5 Mobility: medium-term	2	324	Hedges' g (Random, 95% CI)	0.42 [-0.07, 0.91]
6 Mobility: long-term	3	303	Hedges' g (Random, 95% CI)	0.42 [-0.18, 1.02]

### Comparison 3. Subgroup analysis: Psychological intervention vs attention control group

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: medium-term	3	240	Hedges' g (Random, 95% CI)	0.44 [-0.19, 1.07]
2 Mental distress: long-term	3	350	Hedges' g (Random, 95% CI)	-0.05 [-0.28, 0.18]

**Comparison 4. Subgroup analysis: Psychoeducation vs control condition**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: medium-term	8	785	Hedges' g (Random, 95% CI)	0.39 [0.06, 0.73]
2 Mental distress: long-term	3	462	Hedges' g (Random, 95% CI)	0.28 [-0.13, 0.68]

**Comparison 5. Subgroup analysis: Relaxation vs control condition**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: long-term	2	124	Hedges' g (Random, 95% CI)	0.67 [-0.65, 2.00]

**Comparison 6. Subgroup analysis: Combined intervention vs control condition**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: medium-term	3	309	Hedges' g (Random, 95% CI)	0.05 [-0.16, 0.26]
2 Mental distress: long-term	6	725	Hedges' g (Random, 95% CI)	0.17 [-0.09, 0.43]

**Comparison 7. Sensitivity analysis: Studies with adequate sequence generation**

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: medium-term	4	400	Hedges' g (Random, 95% CI)	0.44 [-0.12, 1.00]
2 Mental distress: long-term	4	523	Hedges' g (Random, 95% CI)	0.15 [-0.20, 0.51]

### Comparison 8. Sensitivity analysis: Studies with adequate handling of incomplete outcome data

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: medium-term	6	612	Hedges' g (Random, 95% CI)	0.15 [-0.07, 0.36]
2 Mental distress: long-term	4	565	Hedges' g (Random, 95% CI)	0.10 [-0.18, 0.37]

### Comparison 9. Sensitivity analysis: Studies with study protocol available

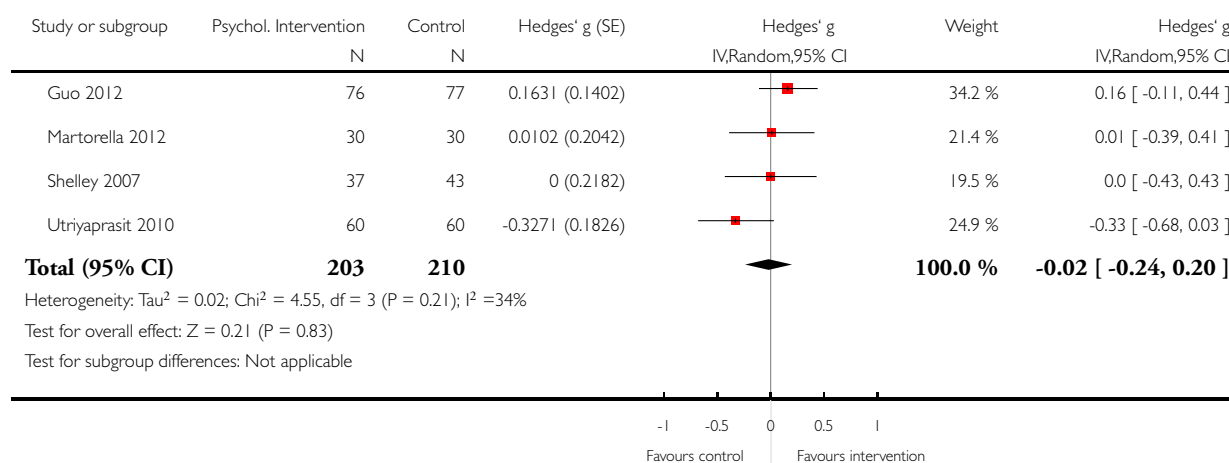
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mental distress: medium-term	2	213	Hedges' g (Random, 95% CI)	0.28 [-0.30, 0.86]

### Analysis 1.1. Comparison 1 Psychological intervention vs control condition, Outcome 1 Pain intensity measured with continuous scales: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 1 Psychological intervention vs control condition

Outcome: 1 Pain intensity measured with continuous scales: medium-term

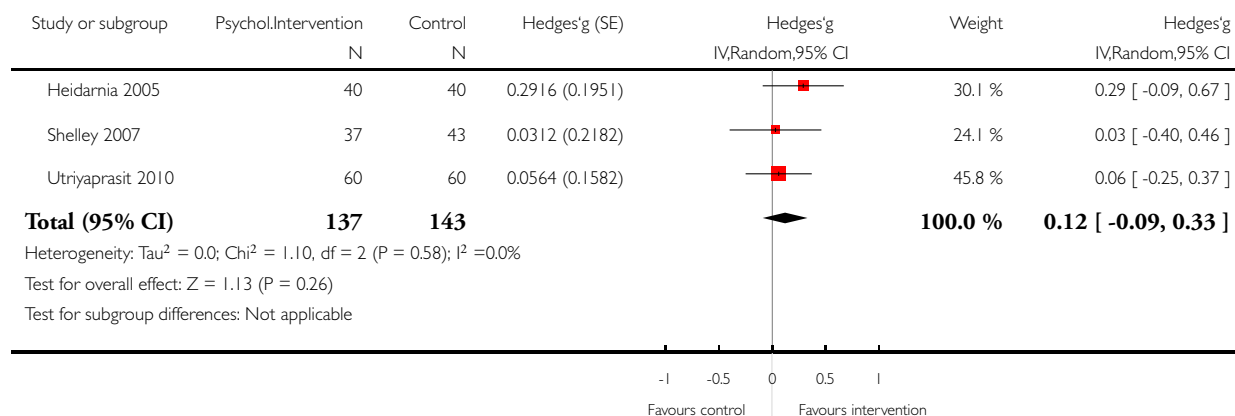


## Analysis 1.2. Comparison 1 Psychological intervention vs control condition, Outcome 2 Pain intensity measured with continuous scales: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 1 Psychological intervention vs control condition

Outcome: 2 Pain intensity measured with continuous scales: long-term



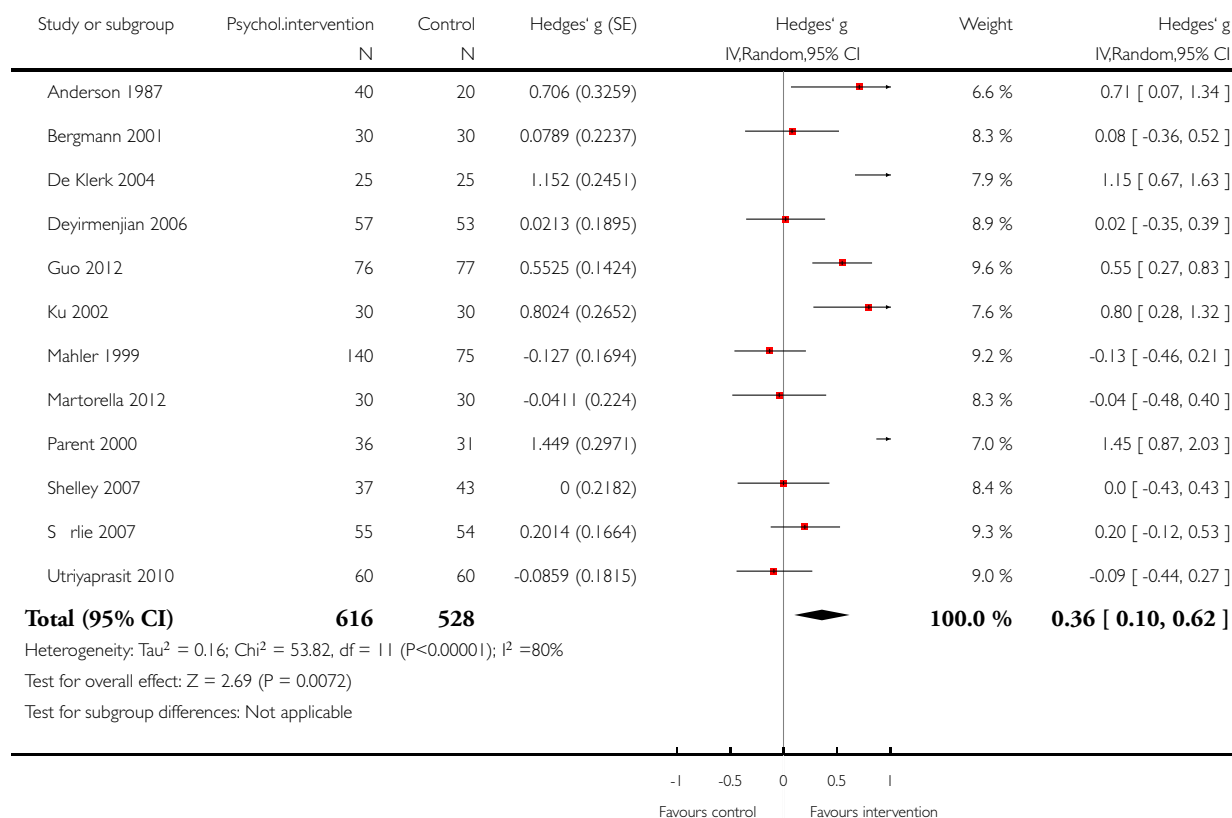


### Analysis 1.3. Comparison 1 Psychological intervention vs control condition, Outcome 3 Mental distress: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 1 Psychological intervention vs control condition

Outcome: 3 Mental distress: medium-term

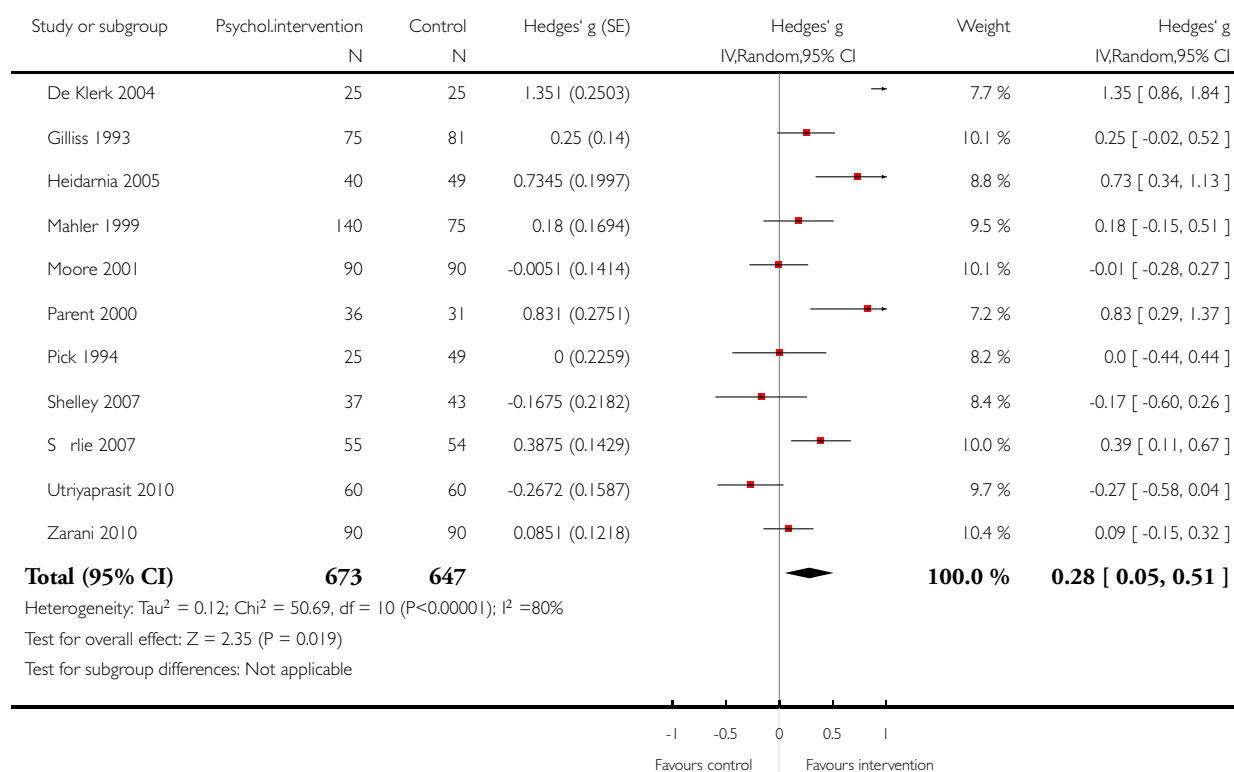


# **Analysis 1.4. Comparison 1 Psychological intervention vs control condition, Outcome 4 Mental distress: long-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 1 Psychological intervention vs control condition

Outcome: 4 Mental distress: long-term

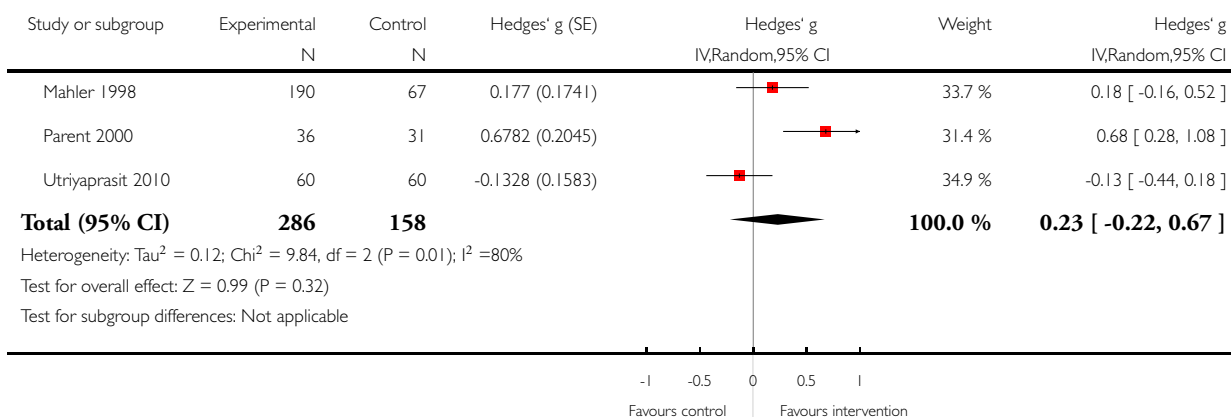


### Analysis 1.5. Comparison 1 Psychological intervention vs control condition, Outcome 5 Mobility: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 1 Psychological intervention vs control condition

Outcome: 5 Mobility: medium-term

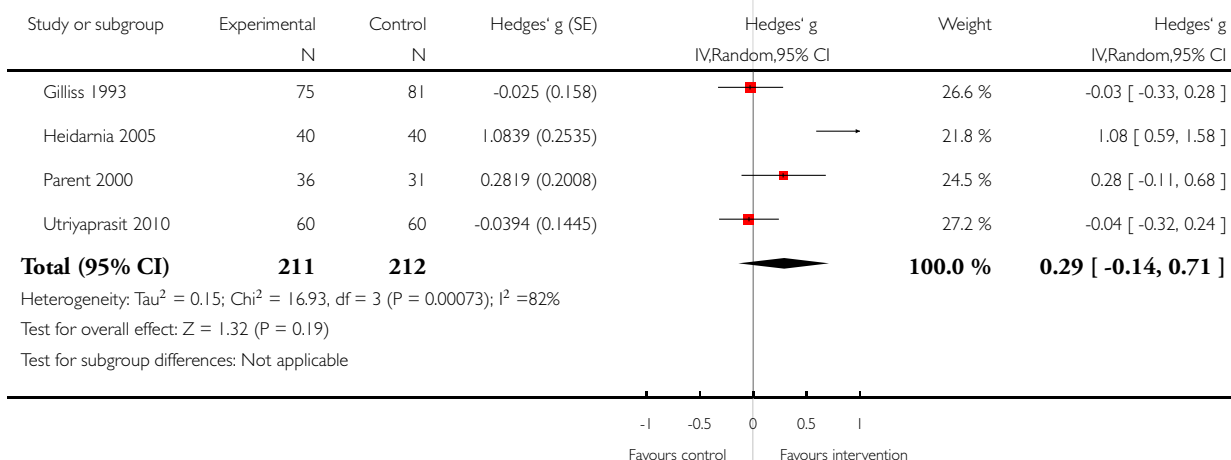


### Analysis 1.6. Comparison 1 Psychological intervention vs control condition, Outcome 6 Mobility: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 1 Psychological intervention vs control condition

Outcome: 6 Mobility: long-term

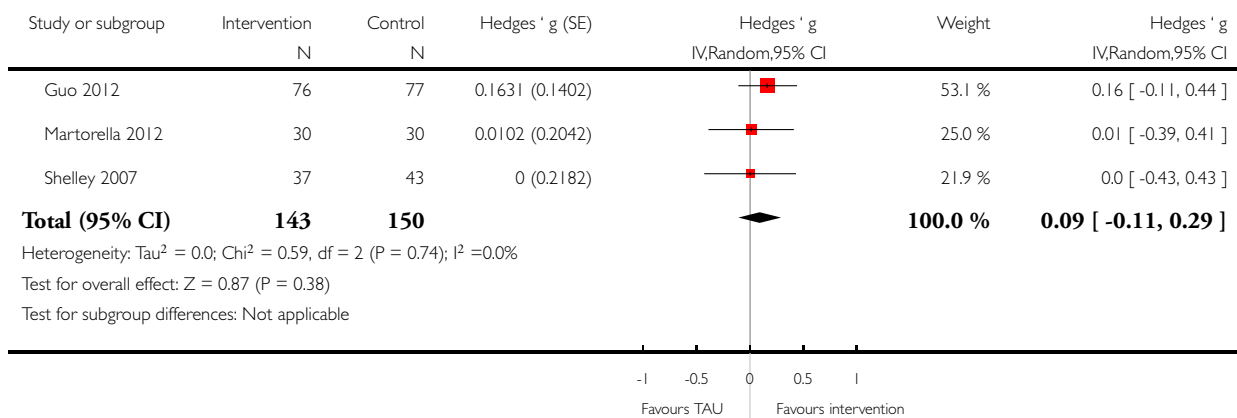


**Analysis 2.1. Comparison 2 Subgroup analysis: Psychological intervention vs standard care (TAU), Outcome 1 Pain intensity measured with continuous scales: medium-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 2 Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome: 1 Pain intensity measured with continuous scales: medium-term

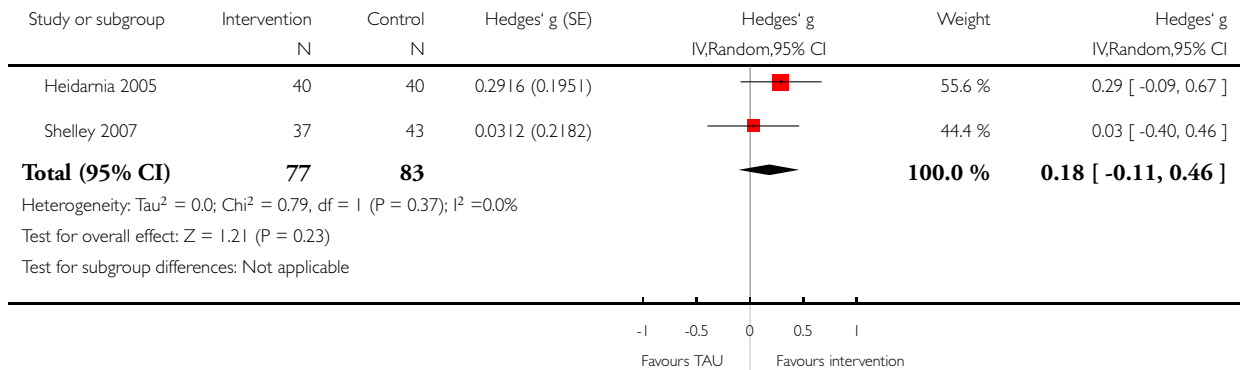


**Analysis 2.2. Comparison 2 Subgroup analysis: Psychological intervention vs standard care (TAU), Outcome 2 Pain intensity measured with continuous scales: long-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 2 Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome: 2 Pain intensity measured with continuous scales: long-term

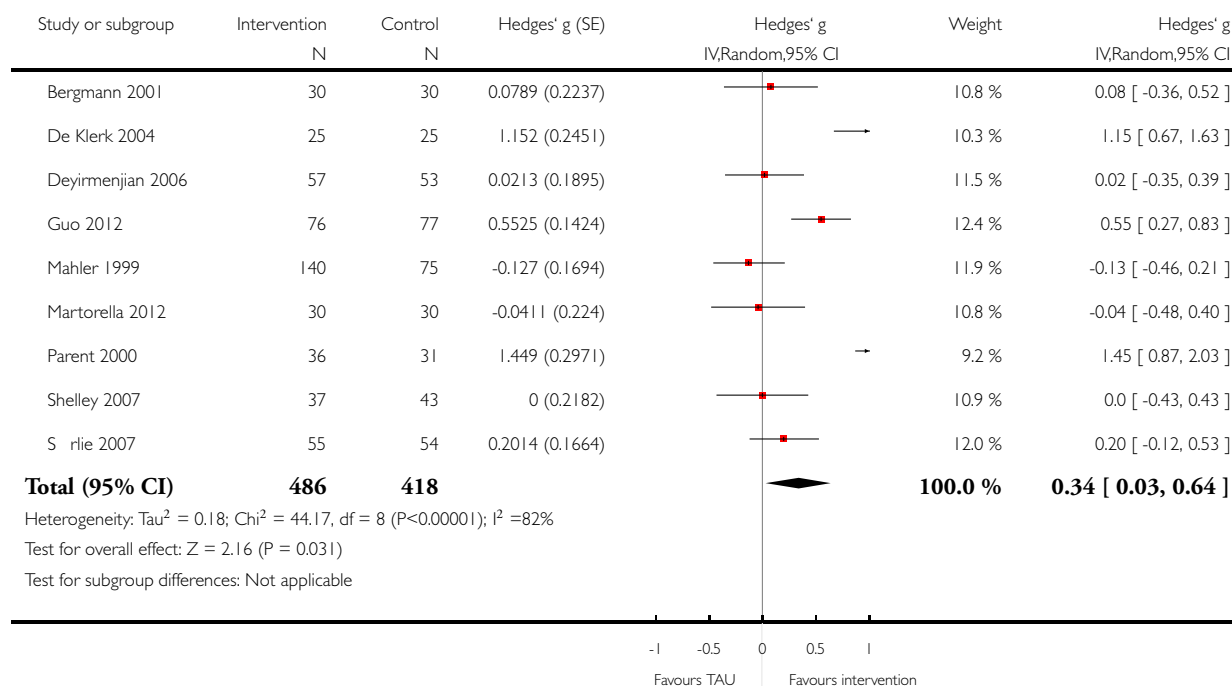


### Analysis 2.3. Comparison 2 Subgroup analysis: Psychological intervention vs standard care (TAU), Outcome 3 Mental distress: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 2 Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome: 3 Mental distress: medium-term

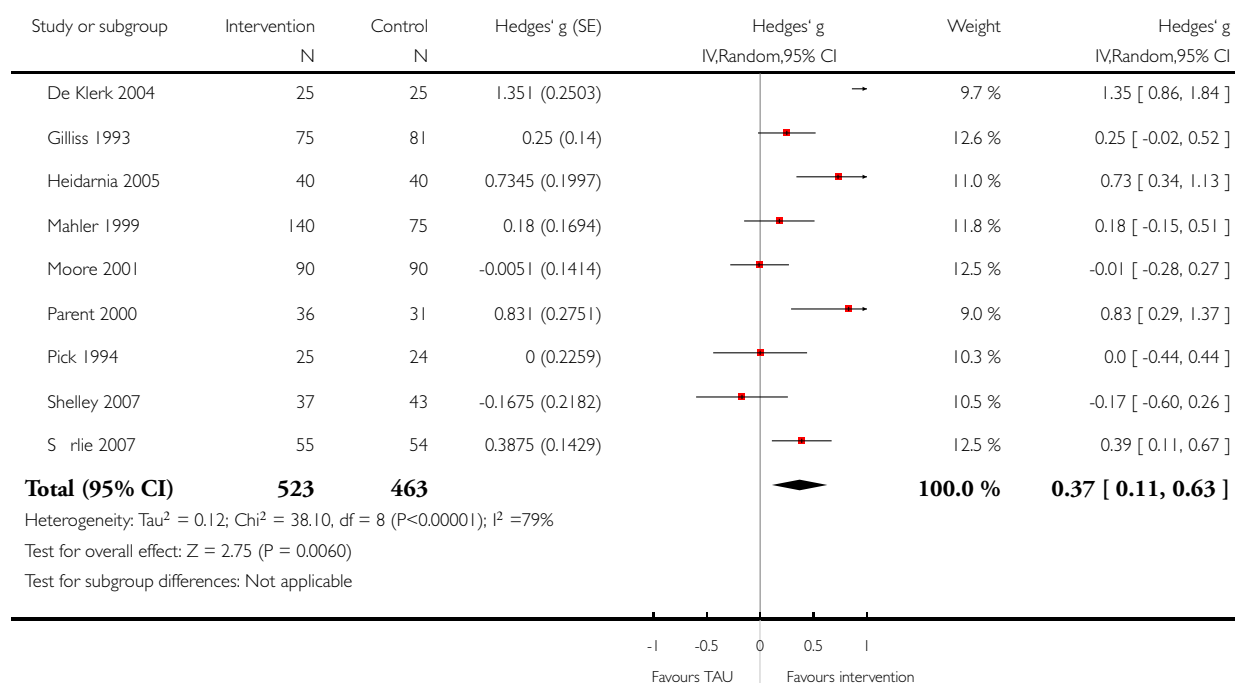


## Analysis 2.4. Comparison 2 Subgroup analysis: Psychological intervention vs standard care (TAU), Outcome 4 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 2 Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome: 4 Mental distress: long-term

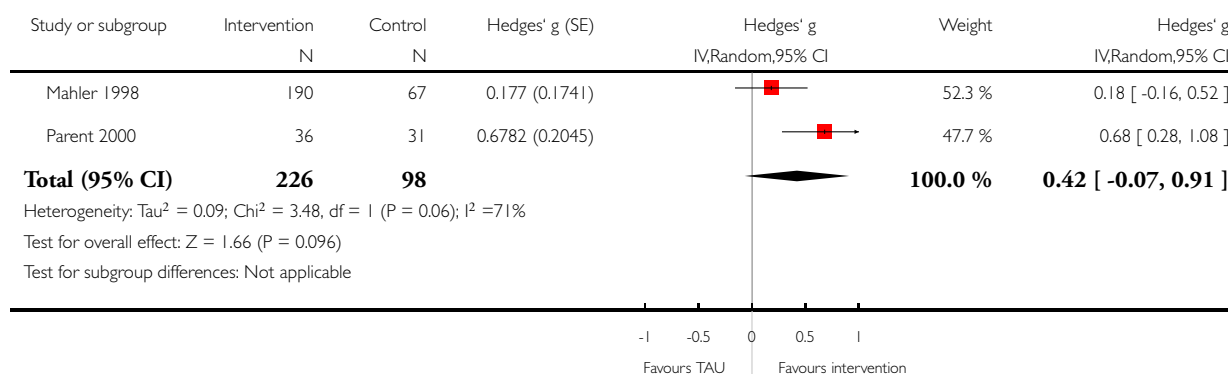


### Analysis 2.5. Comparison 2 Subgroup analysis: Psychological intervention vs standard care (TAU), Outcome 5 Mobility: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 2 Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome: 5 Mobility: medium-term

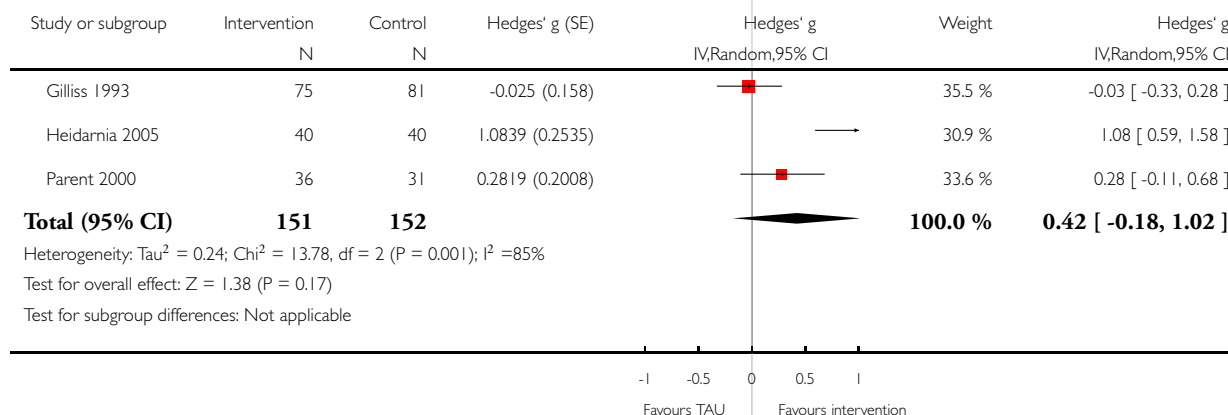


### Analysis 2.6. Comparison 2 Subgroup analysis: Psychological intervention vs standard care (TAU), Outcome 6 Mobility: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 2 Subgroup analysis: Psychological intervention vs standard care (TAU)

Outcome: 6 Mobility: long-term



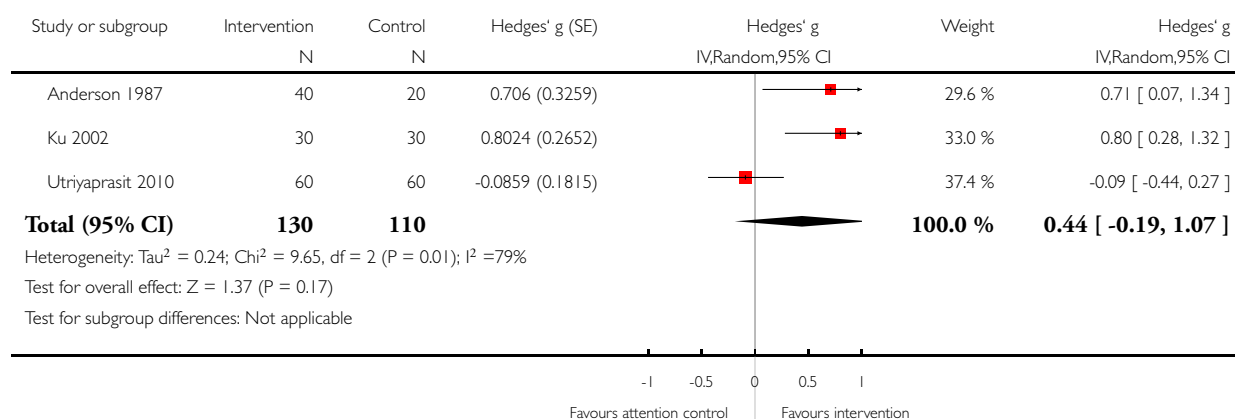


### Analysis 3.1. Comparison 3 Subgroup analysis: Psychological intervention vs attention control group, Outcome 1 Mental distress: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 3 Subgroup analysis: Psychological intervention vs attention control group

Outcome: 1 Mental distress: medium-term

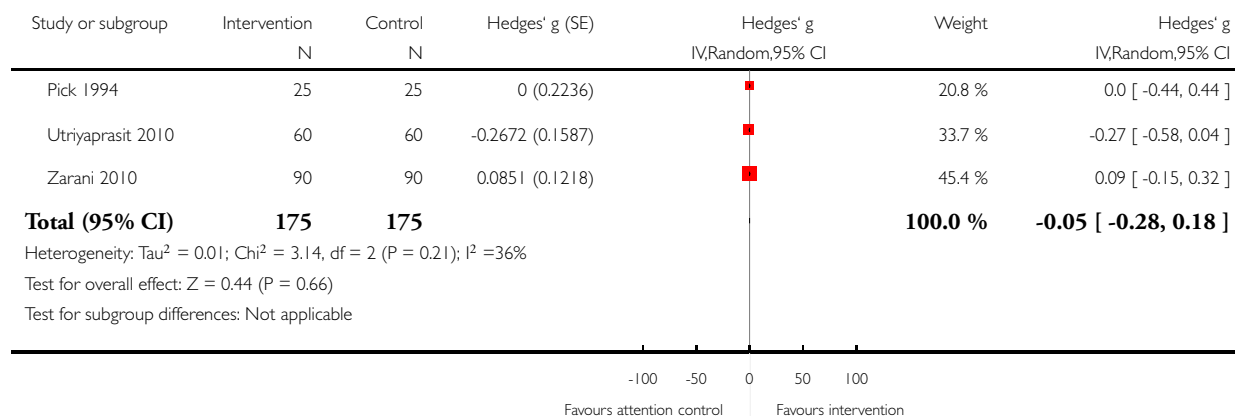


### Analysis 3.2. Comparison 3 Subgroup analysis: Psychological intervention vs attention control group, Outcome 2 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 3 Subgroup analysis: Psychological intervention vs attention control group

Outcome: 2 Mental distress: long-term

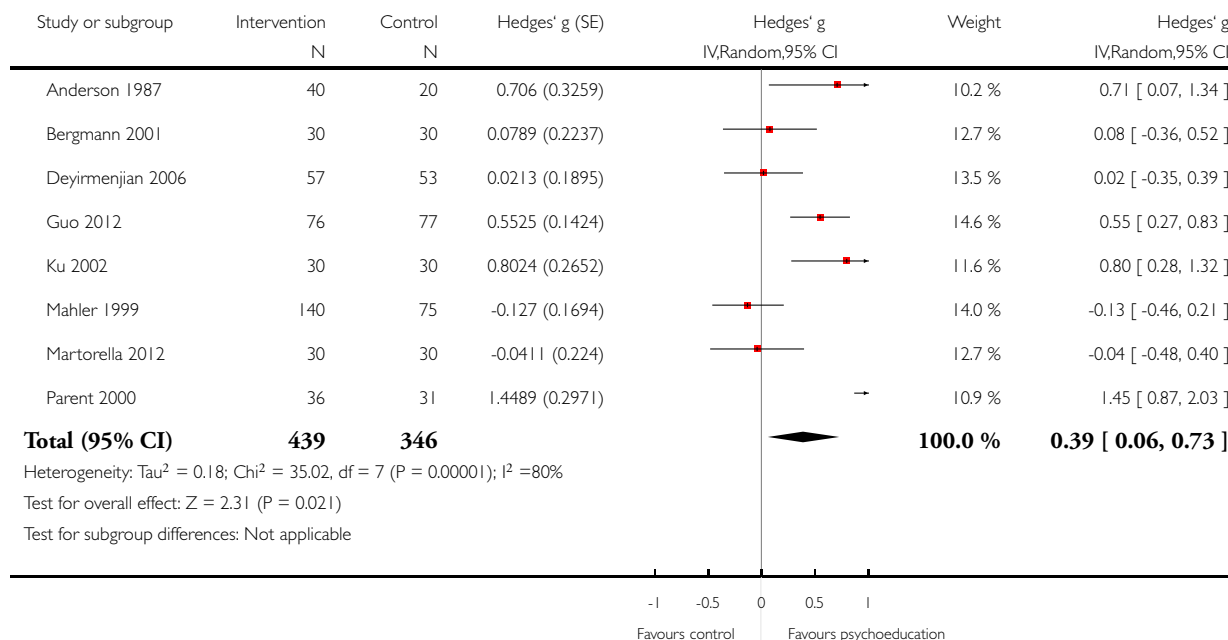


# **Analysis 4.1. Comparison 4 Subgroup analysis: Psychoeducation vs control condition, Outcome 1 Mental distress: medium-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 4 Subgroup analysis: Psychoeducation vs control condition

Outcome: 1 Mental distress: medium-term

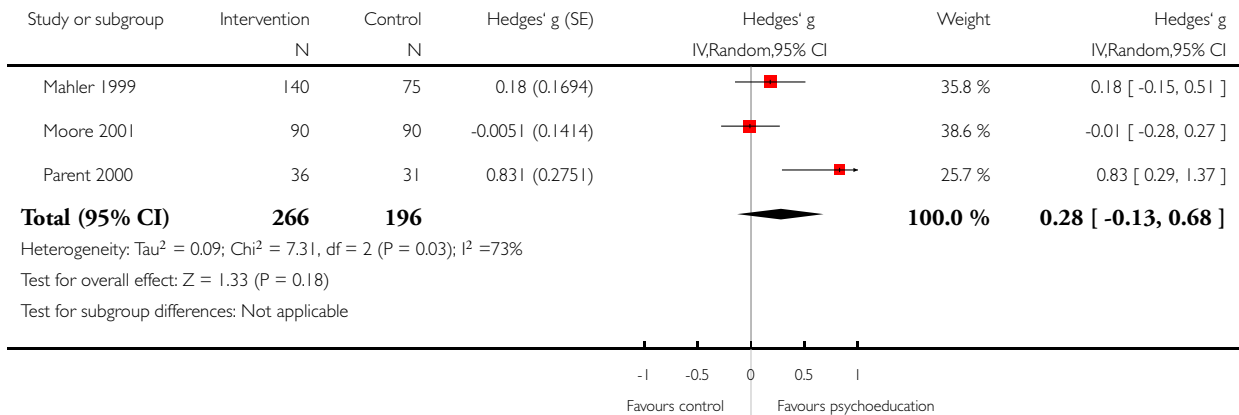


#### Analysis 4.2. Comparison 4 Subgroup analysis: Psychoeducation vs control condition, Outcome 2 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 4 Subgroup analysis: Psychoeducation vs control condition

Outcome: 2 Mental distress: long-term

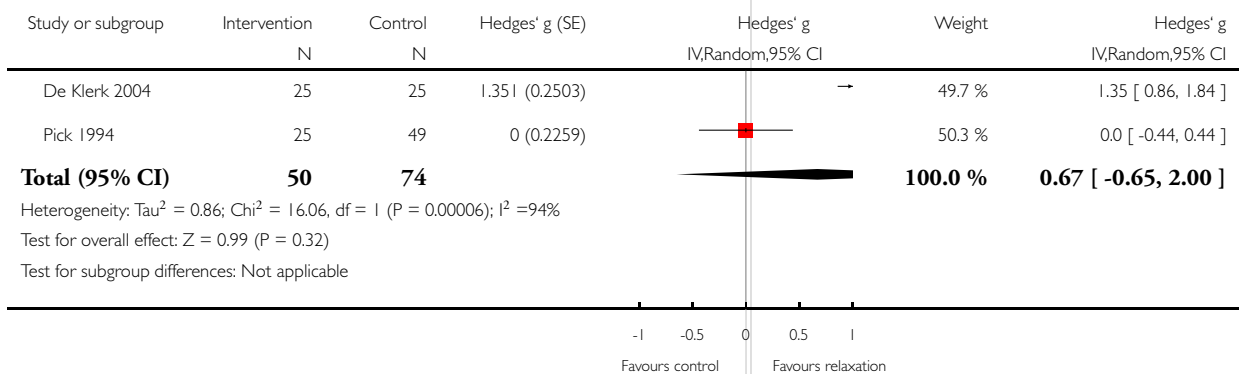


#### Analysis 5.1. Comparison 5 Subgroup analysis: Relaxation vs control condition, Outcome 1 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 5 Subgroup analysis: Relaxation vs control condition

Outcome: 1 Mental distress: long-term

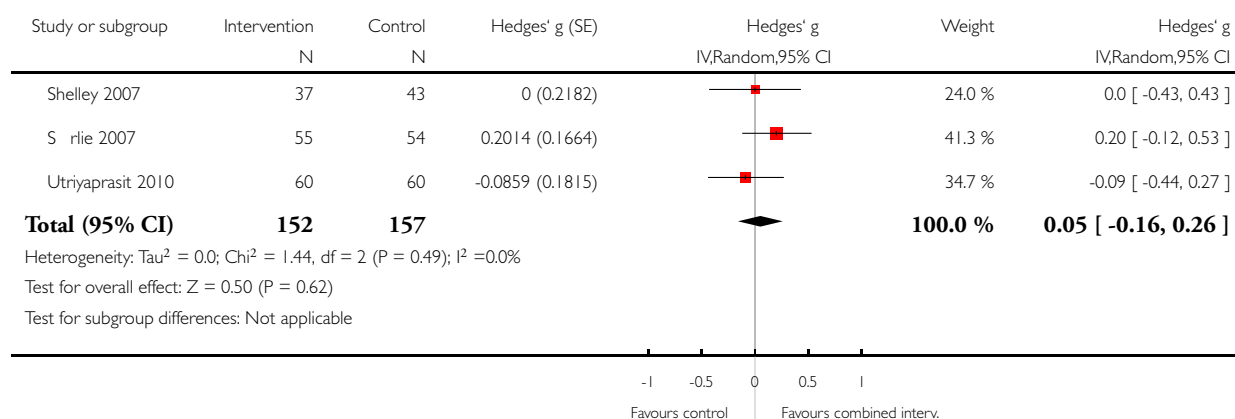


# **Analysis 6.1. Comparison 6 Subgroup analysis: Combined intervention vs control condition, Outcome 1 Mental distress: medium-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 6 Subgroup analysis: Combined intervention vs control condition

Outcome: 1 Mental distress: medium-term

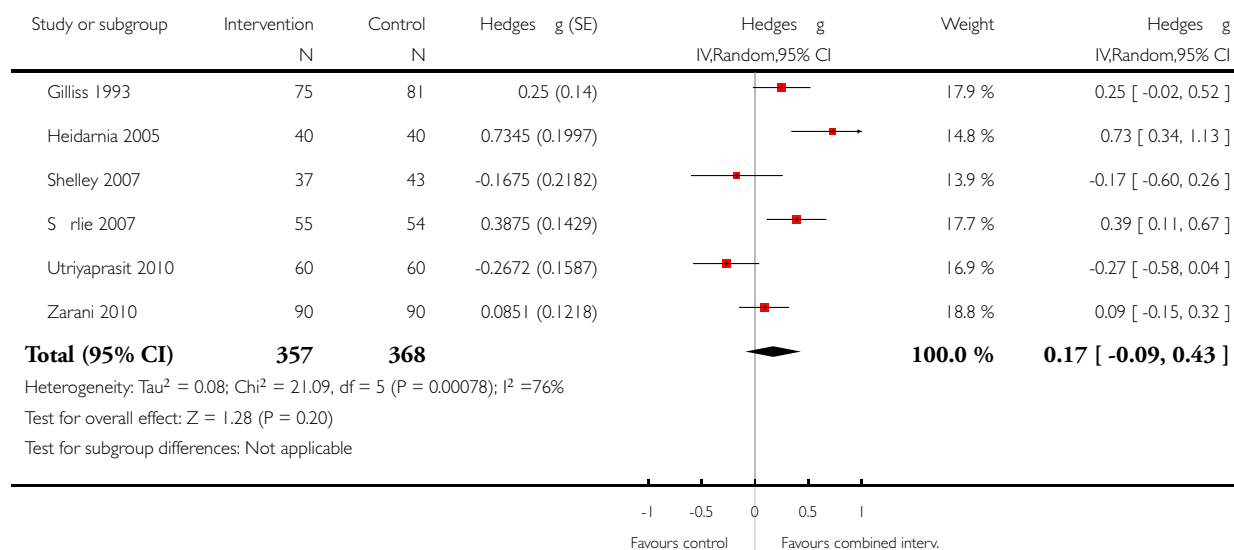


## Analysis 6.2. Comparison 6 Subgroup analysis: Combined intervention vs control condition, Outcome 2 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 6 Subgroup analysis: Combined intervention vs control condition

Outcome: 2 Mental distress: long-term

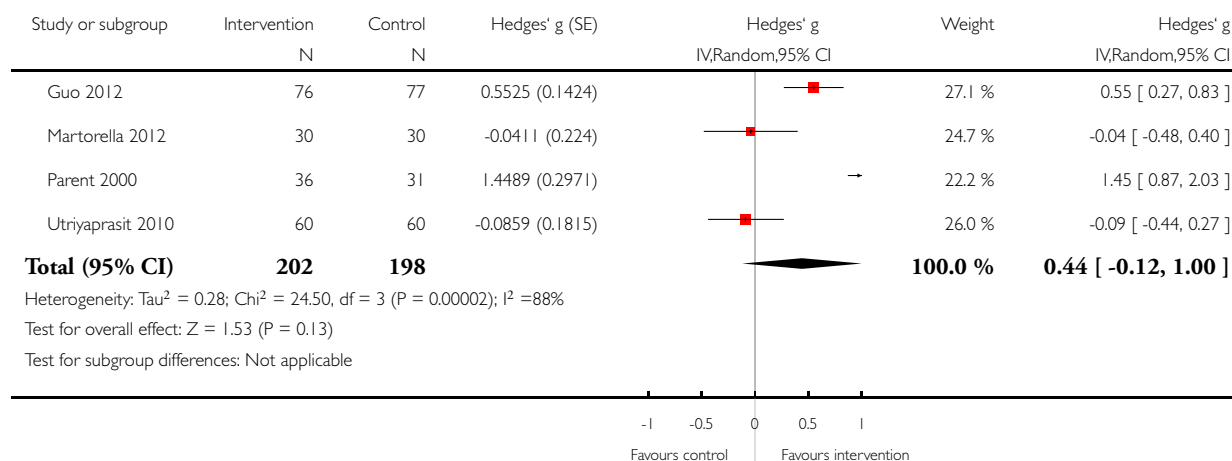


# **Analysis 7.1. Comparison 7 Sensitivity analysis: Studies with adequate sequence generation, Outcome 1 Mental distress: medium-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 7 Sensitivity analysis: Studies with adequate sequence generation

Outcome: 1 Mental distress: medium-term

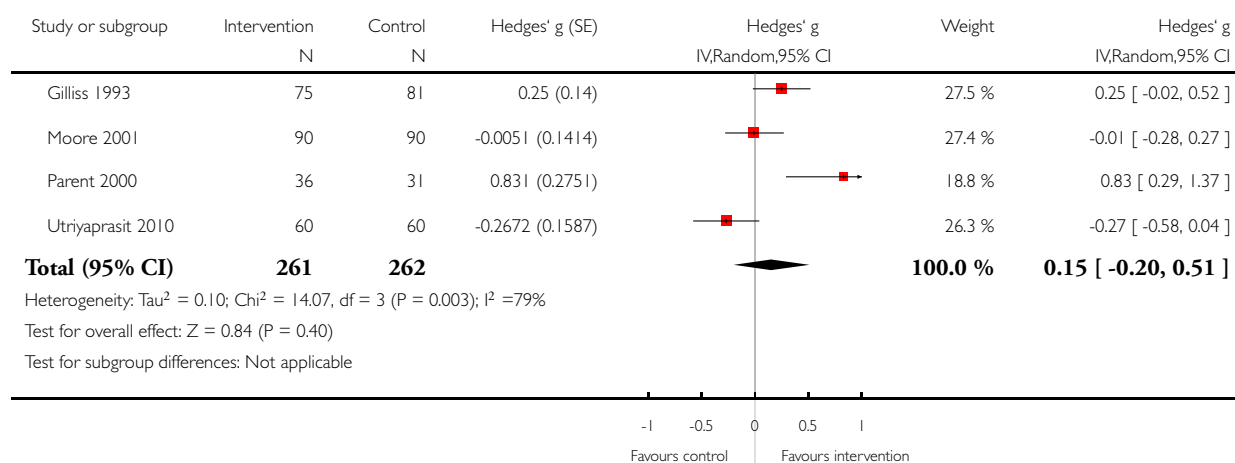


## Analysis 7.2. Comparison 7 Sensitivity analysis: Studies with adequate sequence generation, Outcome 2 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 7 Sensitivity analysis: Studies with adequate sequence generation

Outcome: 2 Mental distress: long-term



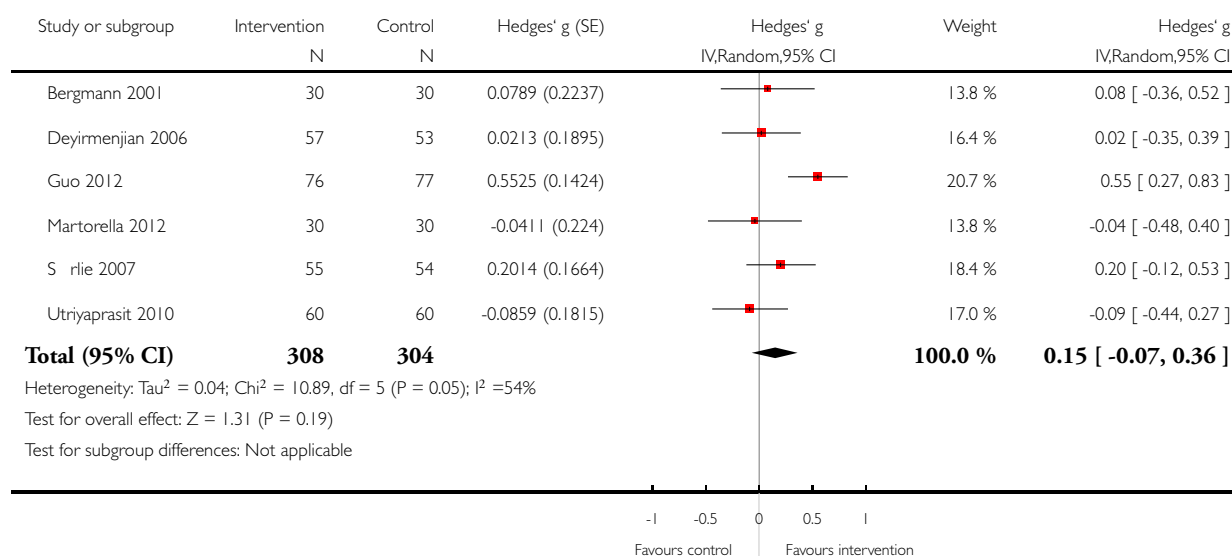


# **Analysis 8.1. Comparison 8 Sensitivity analysis: Studies with adequate handling of incomplete outcome data, Outcome 1 Mental distress: medium-term.**

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 8 Sensitivity analysis: Studies with adequate handling of incomplete outcome data

Outcome: 1 Mental distress: medium-term

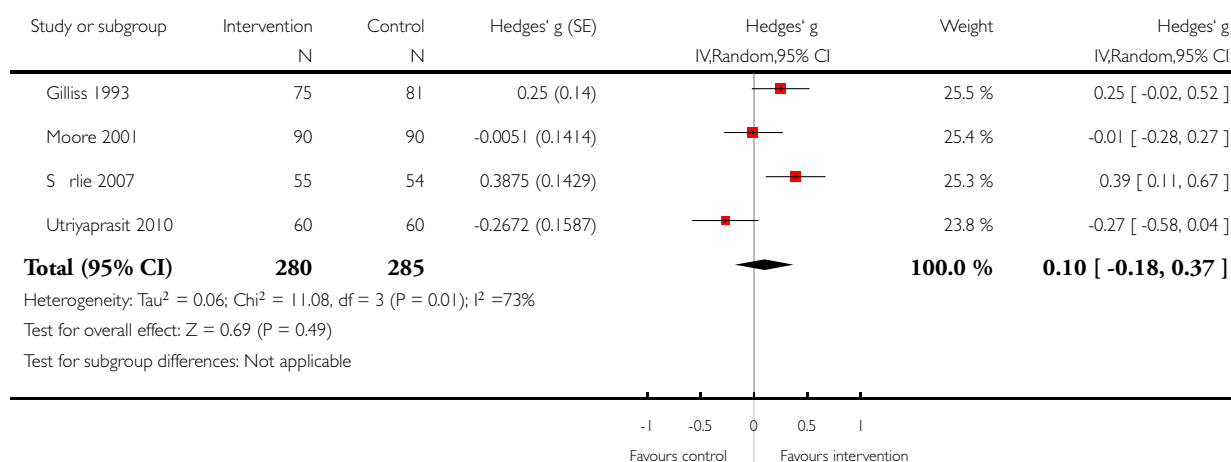


## Analysis 8.2. Comparison 8 Sensitivity analysis: Studies with adequate handling of incomplete outcome data, Outcome 2 Mental distress: long-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 8 Sensitivity analysis: Studies with adequate handling of incomplete outcome data

Outcome: 2 Mental distress: long-term

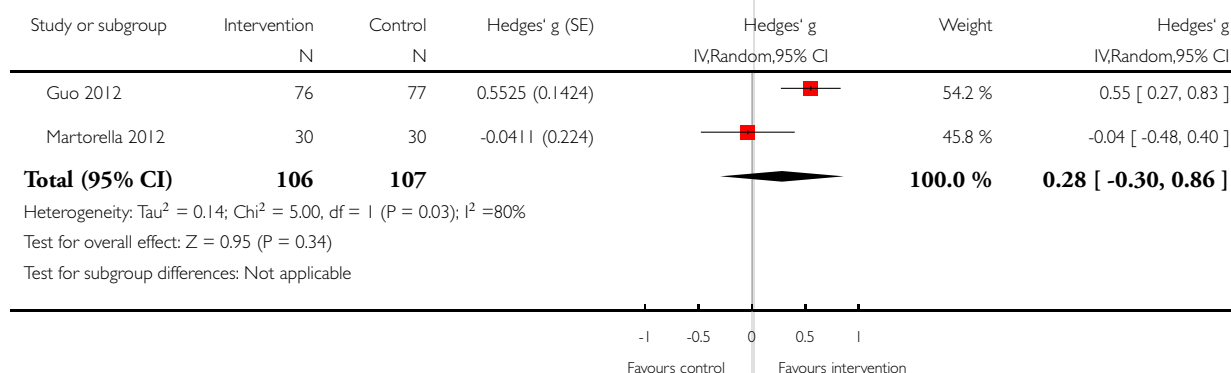


## Analysis 9.1. Comparison 9 Sensitivity analysis: Studies with study protocol available, Outcome 1 Mental distress: medium-term.

Review: Psychological interventions for acute pain after open heart surgery

Comparison: 9 Sensitivity analysis: Studies with study protocol available

Outcome: 1 Mental distress: medium-term



## ADDITIONAL TABLES

Table 1. Postoperative complications

Martorella 2012	Deyirmenjian 2006	Parent 2000
Postoperative complications (not specified)	Pulmonary complications	Postoperative complications
Intervention n = 13 (45%)	Intervention n = 0	Intervention 11% (pulmonary oedema, peripheral embolism, intestinal reocclusion)
Control n = 15 (68%)	Control n = 1 (1.8%)	
	Thrombosis	
	Intervention n = 0	Control 6.5% (pulmonary oedema)
	Control n = 0	
	Psychosis	
	Intervention n = 2 (3.8%)	
	Control n = 1 (1.8%)	
	Other complications	
	Intervention n = 7 (13.2%)	
	Control n = 8 (14%)	

## APPENDICES

### Appendix I. MEDLINE search strategy

- 1 exp Pain/
- 2 Pain, Postoperative/
- 3 pain\*.mp.
- 4 1 or 2 or 3
- 5 exp Cardiac Surgical Procedures/
- 6 Sternotomy/ or sternotomy.mp.
- 7 Thoracotomy/ or thoracotomy.mp.
- 8 Cardiopulmonary Bypass/
- 9 (CABS or CABG).mp.
- 10 ((heart\* or coronary or cardio\* or cardiac or valve\* or congenital lesion\* or thoracic aorta) adj5 (surg\* or intervention\* or procedure\* or bypass\*)).mp.
- 11 5 or 6 or 7 or 8 or 9 or 10
- 12 Patient Education as Topic/
- 13 (inform\* or educat\* or psychoeducat\* or knowledge\* or instruct\* or communicat\*).mp.
- 14 exp Psychotherapy/
- 15 exp Mind-Body Therapies/
- 16 (psychotherap\* or psychologic\* or behaviour\* or behavior\* or cognit\*).mp.

17 (problem adj5 solv\*).mp.  
 18 (relax\* or breath\*).mp.  
 19 (hypno\* or self-hypno\* or auto-hypno\* or suggest\* or (autogenic adj5 train\*)).mp.  
 20 (imag\* or attention\* or distract\* or visuali\* or reframe\* or reapprais\*).mp.  
 21 Emotions/ or emotion\*.mp.  
 22 (cope or coping or counsel\*).mp.  
 23 ((stress\* or anxiety or anxious\*) adj5 (manag\* or therap\* or treat\*)).mp.  
 24 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23  
 25 4 and 11 and 24  
 26 randomized controlled trial.pt.  
 27 controlled clinical trial.pt.  
 28 randomized.ab.  
 29 placebo.ab.  
 30 clinical trials as topic.sh.  
 31 randomly.ab.  
 32 trial.ti.  
 33 26 or 27 or 28 or 29 or 30 or 31 or 32  
 34 25 and 33

key:

mp = protocol supplementary concept, rare disease supplementary concept, title, original title, abstract, name of substance word, subject heading word, unique identifier

pt = publication type

ab = abstract

sh = subject heading

it = title

## Appendix 2. CENTRAL search strategy

#1 MeSH descriptor Pain explode all trees  
 #2 MeSH descriptor Pain, Postoperative, this term only  
 #3 pain\*  
 #4 (#1 OR #2 OR #3)  
 #5 MeSH descriptor Cardiac Surgical Procedures explode all trees  
 #6 MeSH descriptor Sternotomy, this term only  
 #7 sternotomy  
 #8 MeSH descriptor Thoracotomy, this term only  
 #9 thoracotomy  
 #10 MeSH descriptor Cardiopulmonary Bypass, this term only  
 #11 CABS or CABG  
 #12 (heart\* or coronary or cardio\* or cardiac or valve\* or congenital lesion\* or thoracic aorta) near/5 (surg\* or intervention\* or procedure\* or bypass\*)  
 #13 (#5 OR #6 OR #7 OR #8 OR #8 OR #10 OR #11 OR #12)  
 #14 MeSH descriptor Patient Education as Topic, this term only  
 #15 inform\* or educat\* or psychoeducat\* or knowledge\* or instruct\* or communicat\*  
 #16 MeSH descriptor Psychotherapy explode all trees  
 #17 MeSH descriptor Mind-Body Therapies explode all trees  
 #18 psychotherap\* or psychologic\* or behaviour\* or behavior\* or cognit\*  
 #19 problem near/5 solv\*  
 #20 relax\* or breath\*  
 #21 hypno\* or self-hypno\* or auto-hypno\* or suggest\* or (autogenic near/5 train\*)  
 #22 imag\* or attention\* or distract\* or visuali\* or reframe\* or reapprais\*  
 #23 MeSH descriptor Emotions explode all trees

#24 emotion\*  
 #25 cope or coping or counsel\*  
 #26 (stress\* or anxiety or anxious\*) near/5 (manag\* or therap\* or treat\*)  
 #27 (#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26)  
 #28 (#4 AND #13 AND #27)

### Appendix 3. EMBASE search strategy

1 exp pain/  
 2 pain\*.mp.  
 3 1 or 2  
 4 exp heart surgery/  
 5 sternotomy/ or sternotomy.mp.  
 6 thoracotomy/ or thoracotomy.mp.  
 7 cardiopulmonary bypass/  
 8 (CABS or CABG).mp.  
 9 ((heart\* or coronary or cardio\* or cardiac or valve\* or congenital lesion\* or thoracic aorta) adj5 (surg\* or intervention\* or procedure\* or bypass\*)).mp.  
 10 4 or 5 or 6 or 7 or 8 or 9  
 11 patient education/  
 12 (inform\* or educat\* or psychoeducat\* or knowledge\* or instruct\* or communicat\*).mp.  
 13 exp psychotherapy/  
 14 hypnosis/  
 15 (psychotherap\* or psychologic\* or behaviour\* or behavior\* or cognit\*).mp.  
 16 (problem\* adj5 solv\*).mp.  
 17 (relax\* or breath\*).mp.  
 18 (hypno\* or self-hypno\* or auto-hypno\* or suggest\* or (autogenic adj5 train\*)).mp.  
 19 (imag\* or attention\* or distract\* or visuali\* or reframe\* or reapprais\*).mp.  
 20 exp emotion/ or emotion\*.mp.  
 21 (cope or coping or counsel\*).mp.  
 22 ((stress\* or anxiety or anxious\*) adj5 (manag\* or therap\* or treat\*)).mp.  
 23 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22  
 24 3 and 10 and 23  
 25 crossover procedure/  
 26 double-blind procedure/  
 27 randomized controlled trial/  
 28 single-blind procedure/  
 29 random\*.mp.  
 30 factorial\*.mp.  
 31 (crossover\* or cross over\* or cross-over\*).mp.  
 32 placebo\*.mp.  
 33 (double\* adj blind\*).mp.  
 34 (singl\* adj blind\*).mp.  
 35 assign\*.mp.  
 36 allocat\*.mp.  
 37 volunteer\*.mp.  
 38 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37  
 39 24 and 38  
 key:  
 [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword]

#### Appendix 4. PsycINFO (OVID) search strategy

1. exp Pain/
2. pain\*.mp.
3. 1 or 2
4. exp Heart Surgery/
5. Sternotomy/ or sternotomy.mp.
6. Thoracotomy/ or thoracotomy.mp.
7. (CABS or CABG).mp.
8. ((heart\* or coronary or cardio\* or cardiac or valve\* or congenital lesion\* or thoracic aorta) adj5 (surg\* or intervention\* or procedure\* or bypass\*)).mp.
9. 4 or 5 or 6 or 7 or 8
10. Client Education/
11. (inform\* or educat\* or psychoeducat\* or knowledge\* or instruct\* or communicat\*).mp.
12. exp Psychotherapy/
13. exp Mind Body Therapy/
14. (psychotherap\* or psycholog\* or behaviour\* or behavior\* or cognit\*).mp.
15. (problem adj5 solv\*).mp.
16. (relax\* or breath\*).mp.
17. (hypno\* or self-hypno\* or auto-hypno\* or suggest\* or (autogenic adj5 train\*)).mp.
18. (imag\* or attention\* or distract\* or visuali\* or refram\* or reapprais\*).mp.
19. Emotions/ or emotion\*.mp.
20. (cope or coping or counsel\*).mp.
21. ((stress\* or anxiety or anxious\*) adj5 (manag\* or therap\* or treat\*)).mp.
22. or/10-21
23. 3 and 9 and 22
24. clinical trials/
25. (randomis\* or randomiz\*).tw.
26. (random\$ adj3 (allocat\$ or assign\$)).tw.
27. ((clinic\$ or control\$) adj trial\$).tw.
28. ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj3 (blind\$ or mask\$)).tw.
29. (crossover\$ or "cross over\$").tw.
30. random sampling/
31. Experiment Controls/
32. Placebo/
33. placebo\$.tw.
34. exp program evaluation/
35. treatment effectiveness evaluation/
36. ((effectiveness or evaluat\$) adj3 (stud\$ or research\$)).tw.
37. or/24-36

#### Appendix 5. Web of Science (ISI) search strategy

- #14 #13 AND #4 AND #1  
#13 #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5  
#12 Topic=(((stress\* or anxiety or anxious\*) n/5 (manag\* or therap\* or treat\*)))  
#11 Topic=(emotion\* or cope or coping or counsel\*)  
#10 Topic=((imag\* or attention\* or distract\* or visuali\* or refram\* or reapprais\*))  
#9 Topic=((hypno\* or self-hypno\* or auto-hypno\* or suggest\* or (autogenic n/5 train\*)))  
#8 Topic=((relax\* or breath\*))  
#7 Topic=((problem N/5 solv\*))  
#6 Topic=((psychotherap\* or psycholog\* or behaviour\* or behavior\* or cognit\*))  
#5 Topic=((inform\* or educat\* or psychoeducat\* or knowledge\* or instruct\* or communicat\*))

#4 #3 OR #2

#3 Topic=((heart\* or coronary or cardio\* or cardiac or valve\* or congenital lesion\* or thoracic aorta) N/5 (surg\* or intervention\* or procedure\* or bypass\*))

#2 Topic=(sternotomy or thoracotomy or CABS or CABG)

#1 Topic=(pain\*)

## CONTRIBUTIONS OF AUTHORS

SK: Drafted protocol, developed a search strategy, searched for studies, obtained copies of studies, selected which studies to include, extracted data from studies, entered data into Review Manager 5 ([RevMan 2012](#)), carried out the analysis, interpreted the analysis, drafted the final write-up of the review.

JB: Interpreted the analysis, methodologist, co-authored sections of the review manuscript.

ST: Offered methodological and statistical advice.

BS: Drafted protocol, co-authored sections of the review manuscript.

JR: Drafted protocol, developed a search strategy, searched for studies, selected which studies to include, extracted data from studies, co-authored sections of the review manuscript.

## DECLARATIONS OF INTEREST

None known.

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## DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None.